

ISO 9001:2015 CHECKLIST

Be prepared for your **ISO 9001** audit with this checklist.

This checklist is based on the structure of ISO 9001:2015 and focuses on sections 4-10 that contain the requirements for achieving certification to ISO 9001.

ORGANIZATIONAL CONTEXT (SECTION 4)

There is clear evidence that the team can...

- ☐ Identify internal and external factors that influence performance, strategic direction, and purpose.
- ☐ Identify opportunities and risks that arise from internal and external factors.
- ☐ Identify expectations of internal and external interested parties.
- ☐ Define scope of quality management system (QMS).
- ☐ Define business processes and how they influence each other.
- ☐ Monitor business processes regularly.

LEADERSHIP (SECTION 5)

There is clear evidence that...

- ☐ Top management is in charge of quality management and ensures its on-going effectiveness.
- ☐ Top management defines, documents, and provides quality policy.
- ☐ Top management ensures that customer needs are understood and met.
- ☐ Top management ensures that legal and regulatory requirements are understood and met.
- ☐ Roles, responsibilities, and authorities are clearly defined, documented, and communicated.

PLANNING (SECTION 6)

There is clear evidence that the team can...

- ☐ Identify and analyze opportunities and risks.
- ☐ Define measures for dealing with opportunities and risks.
- ☐ Define measurable quality goals for all functions, levels, and processes.
- ☐ Quality goals are consistent with quality policy.
- ☐ Define measures to achieve quality goals.
- ☐ Changes to QMS are implemented on the basis of systematic planning.



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SUPPORT (SECTION 7)

There is clear evidence that the team can...

- ☐ Identify necessary resources to set up, maintain, and continuously improve quality management.
- ☐ Determine necessary people and infrastructure for implementation of quality management.
- ☐ Provide process environment for implementation of quality management.
- ☐ Identify and allocate resources to ensure reliable monitoring.
- ☐ Ensure that necessary how-to knowledge is captured and maintained within the organization.
- ☐ Ensure that employees have the necessary skills.
- ☐ Ensure that all persons who carry out tasks under supervision are informed about quality objectives.
- ☐ Have a defined communication strategy (both internal and external).
- ☐ Deal with documented information strategically.

OPERATIONS (SECTION 8)

There is clear evidence that the team can...

- ☐ Determine requirements for products or services and follow a defined process to fulfill them.
- ☐ Communication with customers related to the provision of products and services is clearly defined.
- ☐ Handling of customer property is clearly regulated in the company.
- ☐ Products or services meet all legal and official requirements.
- ☐ Changes to product requirements are always controlled, documented, and communicated.
- ☐ Development process is set up to implement and ensure consistent production.
- ☐ Development process is checked by qualified personnel.
- ☐ Outsourced processes and services meet requirements.
- ☐ Approval process is checked in appropriate phases and timely manner.
- ☐ Non-conforming results are controlled and documented according to a defined plan.

PERFORMANCE EVALUATION (SECTION 9)

There is clear evidence that the team can...

- ☐ Determine what needs to be monitored, measured, analyzed, and evaluated.
- ☐ Identify suitable methods for monitoring customer satisfaction.
- ☐ Carry out holistically planned internal audits to check the effectiveness and maintenance of QMS.
- ☐ Top management consistently monitors and adapts the QMS.

IMPROVEMENT (SECTION 10)

There is clear evidence that the team can...

- ☐ Have a defined procedure for handling non-conformities and complaints.
- ☐ Implement corrective measures and documentation.
- ☐ Continuously improve QMS based on results of monitoring, measurement, analysis, and evaluation.

