

# ISO Checklist

By Campbell Rodriguez

- Requirements
  - The organization established, documented, implemented, and maintained a quality management system in accordance with the ISO requirements.
  - The organization determined the processes needed for the quality management system and their application throughout the organization.
  - The organization determined the sequence and interaction of these processes.
  - The organization determined criteria and methods needed to ensure that both the operation and control of these processes are effective.
  - The organization ensured the availability of resources and information necessary to support the operation and monitoring of these processes.
  - The organization monitored, measured where applicable, and analyzed these processes.
  - The organization implemented the actions necessary to achieve the planned results and continual improvement of these processes.
  - These processes are managed in accordance with the ISO requirements.
  - The organization ensured control over any outsourced processes that affect product conformity with requirements.
  - The type and extent of control of these outsourced processes been defined within the quality management system.
- Documentation Requirements
  - System documentation includes documented statements of quality policy and quality objectives.
  - System documentation includes a quality manual.
  - System documentation includes documented procedures and records required by ISO.
  - System documentation includes documents to ensure the effective planning, operation, and control of its processes.
- Quality Manual Requirements
  - Quality manual includes scope of the quality management system, including details of, and justification for, any exclusions.

- Quality manual includes documented procedures established for the quality management system, or reference to them.
- Quality manual that includes description of the interaction between processes of the quality management system.
- Control of Documents
  - The documents required by the quality management system are controlled.
  - Records (a special type of document) are controlled according to the requirements.
  - A documented procedure has been established to control documents.
  - The documented procedure defines the controls to approve documents for adequacy prior to issue.
  - The documented procedure defines the controls to review, and update as necessary, and re-approve documents.
  - The documented procedure defines the controls to ensure that changes and the current revision status of documents are identified.
  - The documented procedure defines the controls to ensure that relevant versions of applicable documents are available at points of use.
  - The documented procedure defines the controls to ensure that documents remain legible and readily identifiable.
  - Documents of external origin necessary for the planning and operation of the quality management system are identified and their distribution controlled.
  - The documented procedure defines the controls to prevent the unintended use of obsolete documents.
- Control of Records
  - Records are established and controlled to provide evidence of conformity to requirements and of the effective operation of the quality management system.
  - A documented procedure has been established for controlling records.
  - The documented procedure defines the controls needed for the Identification of records.
  - The documented procedure defines the controls needed for the Storage of records.
  - The documented procedure defines the controls needed for the Protection of records.

- The documented procedure defines the controls needed for the Retrieval of records.
- The documented procedure defines the controls needed for the Retention time of records.
- The documented procedure defines the controls needed for the Disposition of records.
- Records are kept legible, readily identifiable, and retrievable.