

BRIEF OVERVIEW

Requirements of a Quality Management System to meet ISO 9001 compliance

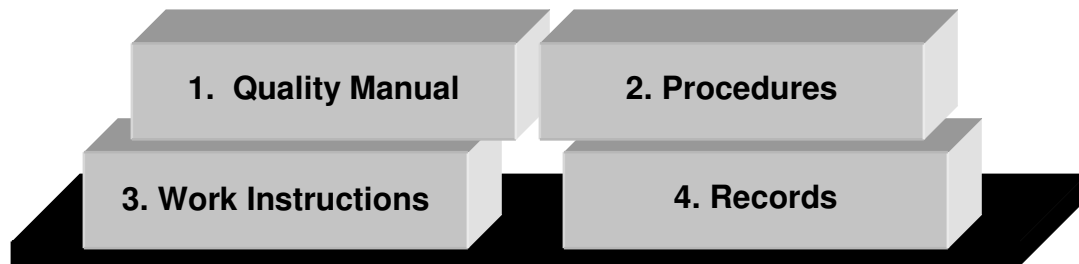
1. Four Levels of Documentation

There is no one way to document your ISO 9000 system. However, documentation is mandatory. It is essential to ISO 9000 since it provides the objective evidence of the work being performed.

With regard to ISO 9000 documentation basically is:

- ♦ Document what you do
- ♦ Perform to the documents
- ♦ Record the results

The four levels of documentation that is most often used to fulfill the ISO 9000 requirements are:



2. ISO 9001 – The Required Documentation

Compliance to ISO 9001:2008

Certain documentation is required in order to comply with ISO 9001:2008. These documents must be controlled. That is the issuance, distribution, and revisions must be controlled.

Required documents:

Quality Documents

- Quality policy (clause 4.2.1.a)
- Quality objectives (clause 4.2.1.a)
- Quality manual (clause 4.2.1.b)

Documented Procedures:

- 4.2.3 Control of documents
- 4.2.4 Control of records
- 8.2.2 Internal audit
- 8.3 Control of nonconforming product
- 8.5.2 Corrective action
- 8.5.3 Preventive action

These documented procedures must be controlled in accordance with the requirements of clause 4.2.3

3. Typical Approach to Achieving ISO 9001 registration:

1. Perform a Gap Analysis (current state vs. future state)
2. Train key employees on mapping the Company's Key and Supporting Processes then map the processes
3. Prepare all documentation utilizing the process maps at the procedure and work instruction level
4. Train personnel on implementing the QMS. Implement the quality management system, and begin internal auditing after your system has been implemented 1 to 3 months. Rework as necessary.
5. Perform one full round on internal audits (all procedures & work instructions). Check all objective evidence (records) against the procedures and work instructions. Rework as needed.
6. Upon completion of the internal audit, a management review must be done; address any corrective actions at this time.
7. Schedule your registration pre-assessment & audit.