BlueSkye Track, Inc.

*Quality, Supply Chain & Lean Six Sigma Solutions*

# BRIEF OVERVIEW

## 1. ISO 9001: 2008 a system of processes

The Quality Management System (QMS) ISO 9001: 2008 is a standard that guides an organization to:

- set up a system of processes,
- determine the linkage of the processes, and
- maintain the processes in compliance with the standard

A quality management system is generally defined as a system of:

- policies,
- processes, and
- instructions

required for planning and execution of development, production and service.

If the QMS is developed and maintained in accordance with the ISO 9001 standard, the organization's QMS can be certified (registered) by a third party called a registrar. Registrars in the U.S. are accredited, to certify companies, in accordance with an organization called ANAB (ANSI-ASQ National Accreditation Board).

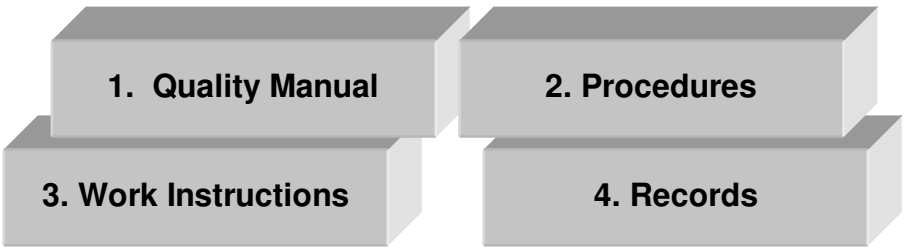
## 2. Four Levels of Documentation

There is no one way to document your ISO 9000 system. However, documentation is mandatory. It is essential to ISO 9001 since it provides the objective evidence of the work being performed.

In basic terms, ISO 9001 documentation requires that an organization must:

- Document what it 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:



## 3. 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

**Records:** There are 21 types of records required under ISO 9001.

## 4. Typical Approach to Achieving ISO 9001 registration:

1. Perform a Gap Analysis (current state vs. future state)
2. Provide a Management Overview of ISO 9000 to key management
3. Map the Company's Core and Supporting Processes.
4. Prepare the Quality Manual including interaction of process diagram. Prepare all documentation utilizing the process maps at the procedure level and work instruction level.
5. Identify all work instructions and records needed for the system
6. Prepare the work instructions.
7. Prepare forms for the records as needed.

8. 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.

9. Perform one full round on internal audits (all processes, procedures & work instructions). Check all objective evidence (records) against the ISO standard, the procedures and work instructions. Rework as needed.

10. Upon completion of the internal audit, a management review must be completed; address any corrective actions at this time.

11. Schedule your registration pre-assessment & audit to be conducted after the management review.

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