ISO 9001:2008: Introduction to the Requirements

Introduction to the Requirements of ISO 9001:2008

The ISO 9001 Standard is organized in five sections or 'Clauses"

Section 4: Quality Management System
Section 5: Management Responsibility
Section 6: Resource Management
Section7: Product Realization
Section 8: Measurement Analysis and Improvement

Today we are going to look at the requirements in Clause 4: General Requirements. The reason we are starting at "4" is because the first three clauses do not have actual requirements; they are more of an introduction to the standard. The requirements are in clauses 4 through 8, where we will focus.

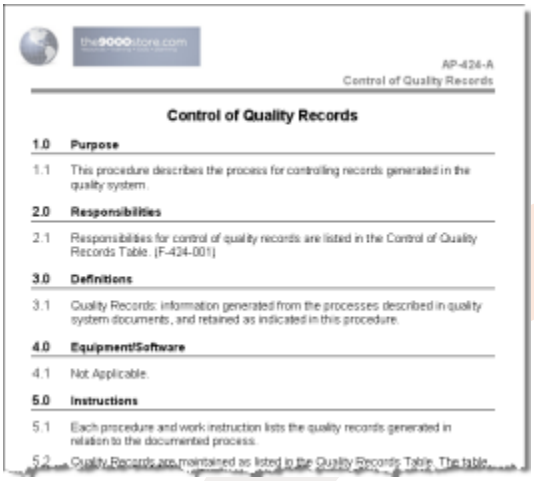
Clause 4: General Requirements

Clause 4.0 gives us the requirements for the foundation or establishment of the Quality Management System (QMS). It tells us to document, implement and maintain the QMS, and continually improve its effectiveness. This section also requires that we write a quality manual and procedures required by the standard. The Quality Policy that we introduced in our last newsletter is required by this clause as well.

Once we have written these documents this clause requires us to control them. Controlling a document means making sure that the current, correct copy is available to employees, and old copies are removed from use right away. Document control is a very important part of ISO 9000.

Procedures

Our organization is writing procedures that explain our processes.



AP-424-A
Control of Quality Records

Control of Quality Records

1.0 Purpose

1.1 This procedure describes the process for controlling records generated in the quality system.

2.0 Responsibilities

2.1 Responsibilities for control of quality records are listed in the Control of Quality Records Table. (F-424-001)

3.0 Definitions

3.1 Quality Records: information generated from the processes described in quality system documents, and retained as indicated in this procedure.

4.0 Equipment/Software

4.1 Not Applicable.

5.0 Instructions

5.1 Each procedure and work instruction lists the quality records generated in relation to the documented process.

5.2 Quality Records are maintained as listed in the Quality Records Table. The table...

We look at each business process, make sure that it meets the requirements of the standard and decide if we need to document it in a procedure.

We will write a procedure to make sure that everyone does the process in the same way, and the correct way. Procedures are an important tool for us to make sure that we have carefully planned how we want to do things, and follow that plan. Procedures are approved by management, and then controlled so employees know that when they follow the procedure they are doing things the correct and approved way.

Procedures are also a good tool for training people on processes. By using our procedures we can improve the consistency and quality of our products.

Watch for our next newsletter for more introduction to ISO 9001:2008, what it will mean to you and your coworkers.

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