

SAMPLE PAGES

FOR

ISO 9001:2000

POCKET GUIDE

MAIN CLAUSE

7

PRODUCT REALIZATION

CLAUSE 7.1

PLANNING OF REALIZATION PROCESSES

PRODUCT
QUALITY
PLANS

In order to minimize the variation of outcomes from processes required for product or service realization, the standard is requiring that they be planned and documented in a way that is compatible with your company's other quality management system processes. As you plan the processes needed for completion of products and/or services, the standard requires determination of the following:

- relevant quality objectives.
- requirements for those products and/or services
- the need for establishment of processes for product and/or service realization
- the requirements for documentation
- the need for resources for the product and /or services to be provided
- activities and criteria to complete verification (testing designs to specifications)
- activities and criteria to complete validation (testing designs to customer performance requirements)
- activities and criteria for monitoring of products and/or services to be provided
- activities and criteria for inspection and testing of products and/or services to be provided

PRODUCT REALIZATION

- recording of evidence of conformity of processes and product. (7.1)

The bulleted list above is a generalized checklist that can be applied when product or service realization processes are initiated or changed. The resulting plan must be in a form that suits the intended task.

Management's Role – As high level managers, it is not likely that you will have the time to entrench yourselves in the details of planning and documenting the above. Nonetheless, the overall responsibility for fulfillment of these requirements is yours. You can, however, grease the path to compliance by encouraging systematic thinking for planning and process development purposes and insisting on dedication to the documented processes during their implementation.

Each Employee's Role – This discussion applies to you if you are working on or in processes for the realization of products or services. Everything that precedes implementation of the process is considered as working on it. Those responsible for implementing the process are working in it.

For those working on, auditors will want to verify that:

- the quality objectives and requirements for product and/or service have been determined.
- a thorough analysis of required processes has been completed.
- a thorough analysis of required documentation has been completed.
- the necessary resources have been predetermined.

PRODUCT REALIZATION

- verification and validation have been pre-planned
- monitoring, testing and inspection have been pre-planned.
- provisions have been made for retaining records of process control and product conformity.

As an employee working in a process, your responsibility is to follow the procedure as written. If you strongly feel that there is a better way to do the job, take the necessary steps to have the procedure changed. Auditors could compare your actual implementation of the process against the current documentation. Should they discover a deviation from a documented procedure, the clarity of the procedure and/or your understanding of the importance of following all procedures will be questioned.



CLAUSE

7.2

CUSTOMER-RELATED PROCESSES

Some of us are born with the ability to sell anything. There are others of us who are trained and become highly skilled at selling specific products or services.

The skills of the sales people can lift the profits of the company. Great results from excellent sales efforts will only be temporary if customer satisfaction is sub optimal. This clause is focused on uncovering and understanding of all customer requirements.

PRODUCT REALIZATION



Determination of requirements related to the product

The standard states that the determination of customer requirements must include:

- product and or service specifications provided by the customer.
- product and or service performance requirements provided by the customer.
- customer stated delivery and beyond requirements.
- determination of application related requirements, if not provided by the customer. For example, the customer may request that the product work equally well in jungles and polar areas. The customer, however, failed to provide specific temperature and humidity requirements.
- determination of relevant legal requirements if any. Your product or service may be subject to codes or regulations coming from agencies like FDA, FAA, EPA etc. All possible levels of jurisdiction, federal, state, local, etc. must be researched..
- determination of relevant environmental requirements if any. These requirements could be legal as above, customer imposed (a customer requirement to be ISO 14000 compliant), agreed to with special interest groups or self-imposed.
- determination of any other relevant requirements (industry standards such as UL and CSA, unique requirements for customers in targeted countries, etc.)

(7.2.1)

Management's Role – Depending on the size of your