# SAMPLE PAGES

# FOR

# ISO 9001:2008

# POCKET GUIDE



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## Preservation of product

Throughout internal processing and delivery, departure from conformity to requirements must be avoided. As needed, preservation includes identification, handling, packaging, storage and protection. Let's examine each category. (7.5.5)

Identification – This topic was thoroughly discussed in clause 7.5.3

Handling - Product must be handled at all stages - from raw material or component stage all the way through final form, shipment and delivery. The standard is simply asking that all handling be such that damage is avoided. Depending on your business, the sensitivities could be to one of many sources including the following: fragility, the environment in the plant or in the process, electrostatic discharge, the environment of the shipping method and simple exposure to the atmosphere.

Packaging – Packaging usually applies to product that is being readied for shipment. It can also apply to raw materials components, subassemblies, partial assemblies etc. Packaging in the broad sense includes the container, the packing materials and the container markings, labels, packing slips, etc. Methods for all packaging need to be such that there is no departure from product conformity. This translates to needs such as: documentation, appropriate control of materials used and design intervention and shipping test where appropriate.

Storage – Storage applies to all levels from raw material

to completed and packaged products. The sensitivities listed above also apply here along with others, depending on the product. One that was not listed above, but is quite commonly a concern here, is time. Products that are sensitive to time will be labeled with a shelf life. The standard is requiring that your company provide stockrooms/storage areas that prevent damage or deterioration. Methods for controlling the contents of those areas should be defined. Periodic assessments of stored materials and products should also be utilized.

Protection – Protection tends to be more generic. Aspects of protection are integral to handling, packaging and storage and apply throughout production and delivery.

The above discussions seemed to be focused on product. Service providers often use materials to complete their services. These requirements apply to those materials. For all of the above, aspects of service must be considered.

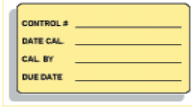
**Management's Role** - The treatments provided to the storage and movement of product should be carefully considered. You cannot recover the cost of customer dissatisfaction from an insurance company. Late deliveries and the arrival of damaged goods are of no use to the customers. Assuring that the requirements of the standard are met will function as the insurance against customer dissatisfaction in this category.

**Each Employee's Role** - Those writing requirements for handling and packaging should have access to data on damage due to these sources so that problems can be solved

and improvements made. Auditors are quick to question handling that appears inappropriate and ask for data to support the methods used.

In the review of product handling, auditors often find problems such as employees who fail to use wrist straps for protecting electronic product from damage caused by electrostatic discharge. Know what your products are sensitive to and take the necessary steps to protect them.

Materials used in the process that have a shelf life and have expired are very easy for auditors to find. Here is a short list of common materials to think about: adhesives, coatings, inks, solder paste and pH buffers. Those of you who support manufacturing, should develop a program for storage and use of limited life materials if appropriate.




## CLAUSE 7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

Calibration can be done internally or through the use of supplied services. When completed by a supplier, the requirements of clause 7.4 apply.

Selecting the correct instrument, based on knowledge of the measurement error and the tolerance of the feature to be measured, is an important requirement in clause 7.6. (7.6)

Whenever an instrument is used, either directly or indirectly, to determine the acceptability of product, ISO

9001:2008 requires calibration and/or verification, if needed, at appropriate intervals using a traceable standard. When needed, calibration includes adjustment. Adjustments must be secured to assure that only authorized technicians readjust during the calibration process. The calibration status of measuring equipment must be determinable. The impact of the environment and handling need to be considered for all measuring equipment. This can be determined through the manufacturer's documentation or by testing its robustness. (7.6)

Reacting to the discovery of measurement equipment that are out of calibration by re-verifying previous results is an extremely important requirement in this clause. The reaction must embrace both the equipment and the product or service. Depending on the product, the consequences of not reacting could be quite serious. The reaction might require measures as drastic as a product recall or field repair. (7.6)

Software, for the purpose of measuring and monitoring, must be approved for use. (7.6)

**Management's Role** - Understanding that wholesale calibration of all devices at arbitrary intervals might be simultaneously costly (too frequent or not required) and risky (too infrequent), management must encourage and provide for a calibration program that includes all considerations found in clause 7.6. Not doing so could directly compromise the quality of the products. There is also an indirect threat to the quality of products when calibration of instruments used for process control measurements is