

SAMPLE PAGES

FOR

AS9100B

POCKET GUIDE

QUALITY MANAGEMENT SYSTEM

documents). The uncontrolled “on the wall” documents are very easy for auditors to find. Throughout the constant vigil on documentation, auditors are also assessing the ability to identify, retrieve and read documents.

Those of you functioning in positions with responsibility for document control must assure that your procedures support all of the requirements of the “Life Cycle” for all document types and that they are implemented. As an auditor, I have, at pre-assessment and registration audits, used the life cycle matrix analysis tool (shown earlier in this element discussion) to assess the thoroughness of a company’s document control procedures.

Auditors sometimes take a fairly large sample of documents from the points of use and verify that they are of the correct revision by checking them in the manner prescribed the quality management system.

Practicing good document control should never be considered an inconvenience.



Control of records

Almost all the records requirements appear in the string of activities found in this requirement: identification, protection, storage, retrieval, retention time and disposition. Guidance is not provided on the retention times in ISO 9001:2000. Depending on the record, direction could be available from your legal department or your customers. Record retention times could also be specified in regulatory documents or other requirements that apply to your business. The required procedure for control of records must address the

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means by which supplier created records are retained by your company and/or the supplier. (4.2.4)

The standard provides direction, as to which records should be included, in two ways: (1) Records are required to demonstrate that requirements are met. (2) Records are required to show that the quality management system is effective. (4.2.4)

More help is provided throughout the standard. Wherever the note “(see 4.2.4)” appears, there is a definite requirement for records. The design of your quality system can also determine the need for other records. (4.2.4)

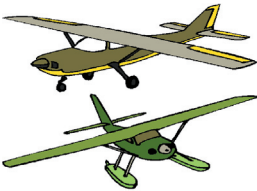
Typically, records are kept in the areas where they originate and archived as space runs low. Your company must assure availability of all records to customer and regulatory representatives in accordance with contract and/or regulatory requirements. (4.2.4)

Management’s Role - This clause has direct impact on management because of the requirement to maintain records of Management Review. Management must clearly define what is to be included in the category of records referred to as Management Review records. Auditors often find that the meeting minutes are the only documents kept. Supporting reports and data not retained otherwise are sometimes omitted. As stated above, one of the reasons for records is to show quality management system effectiveness. The effectiveness of the quality management system is determined by management.

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Each Employee's Role - There are many reasons to be very attentive to your record keeping responsibilities. Among them are issues of traceability, company legal reasons, continuous improvement and assuring that management has good data for evaluation and decision making purposes.

The more general requirements like protection, storage and retrieval will certainly be of interest to auditors. Be prepared, for example, to discuss the way in which you back-up electronic records. Auditors may also want to verify the existence and completeness of each record the standard and your documentation calls for.



CLAUSE 4.3

CONFIGURATION MANAGEMENT

In manufacturing, there are two basic configuration questions. In one case, like base product can be configured

differently to create different end products. In the second case, the same end product may exist at different revision levels. The two airplanes above are two different end products because they have different performance requirements. There is also a need to know the delivered revision level. These two pieces of information are important for such reasons as design input required (i.e. safety) modifications. For this reason, AS9100B requires that your company create or adopt a configuration management process suitable for the products involved. This documented process must be maintained to ensure its continued accuracy. (4.3)

Management's Role - Managers are certainly responsible for the establishment of a suitable configuration management system. That responsibility might require assuring the training of key individuals to attain configuration management skills and/or approving the procurement of configuration management software.

Each Employee's Role - Those of you given the responsibility to update and maintain product configuration will certainly be tested by the auditors. Auditors could and no doubt will select in-process product, in-stock product and maybe delivered product to verify correct configuration information is recorded in accordance with your company's procedure.