

SAMPLE PAGES

FOR

ISO 13485:2003

POCKET GUIDE

product. The method used in either case must comply with the need to assure the ongoing ability of the process to deliver the desired product. (8.2.3)

Let us remain cognizant that the requirement for monitoring and measurement of processes extends beyond just product specific processes to all processes of the quality management system. (8.2.3)

Management's Role – By following the words of Dr. Deming, “Focus on the Process, not on the Outcome”, we give ourselves the opportunity to avoid making defective material or providing inadequate service. Place your priorities for control on process control. The rewards are almost always greater.

Each Employee's Role – The discussion offered in clause 8.1 also applies here.



Monitoring and measurement of product

General requirements

GENERAL REQUIREMENTS During the processes to create product or deliver services, there is a need to measure and monitor product or service results where appropriate. The appropriate places for measurement and monitoring are driven by the risk of moving forward with no knowledge of the quality to that point. The plans for these measuring and monitoring

MEASUREMENT, ANALYSIS AND IMPROVEMENT activities are completed during the planning of realization processes (see clause 7.1). Documented procedures are required for implementation of planned monitoring and measurement activities. The standard clearly states the need to express the evidence of conformity in a manner that allows a comparison of results to the specifications. This record, also containing the record of authority (by job assignment, inspector, auditor, supervisor, manager, etc.) for release to the next stage or to the customer, must be retained. Completed product may only be shipped when all plans have been successful. (8.2.4.1)

Management's Role – As the requirement states, there is a need to measure and monitor the product or service. The amount of inspection and testing needed is a function of the confidence that you have in the process. We already know that confidence can be boosted significantly by the process control techniques discussed so far. Again I encourage you to follow the words of Dr. Deming, “Focus on the Process, not on the Outcome”.

Each Employee's Role - First and foremost, employees, implementing product inspection, must strive to implement the product quality plans just as they have been written. Augmenting the plan with extra inspection is additive to the cost of the product. If you strongly feel that additional inspection is required to assure that customer satisfaction is achieved and sustained, take the necessary steps to have the quality plan changed. Short cutting on any product quality plans is more detrimental than over inspection. In this case, customer dissatisfaction and loss of business could occur. Auditors will surely compare the actual

Auditors might also sample inspection records. They would be looking for such things as evidence that shipment was preceded by completion of the process and authorization to ship.



Particular requirement for active implantable medical devices and implantable medical devices

Again, these two categories of medical devices are in need of special consideration. Active implantable medical devices and implantable medical devices carry a requirement for identifying all individuals conducting inspection or test of these devices. The difference between this requirement and that of 8.2.4.1 is that each individual associated with each testing and inspection activity must be identified. 8.2.4.1 is addressing only that testing that occurs at the release points. The standard leaves no doubt that everyone making a decision on any aspect of acceptability of these devices is known. (8.2.4.2)

Management's Role – I am sure that the highly critical nature of these devices is well understood by management. Management must support the creation of a mistake free environment for determining acceptability of implantable devices. The skills of the inspectors and testers must be optimized through all possible means.

Each Employee's Role - As inspectors and testers of implantable medical devices, you are very likely in a position where your decision could have impact on the well

MEASUREMENT, ANALYSIS AND IMPROVEMENT being of a recipient of a device that you have inspected or tested. An auditor reviewing the records will look for a complete record showing that all inspection and testing of implantable devices can be traced to the individual that conducted it.

SORT

SCRAP

REWORK

REGRADE

REPAIR

USE AS IS

CLAUSE

8.3

**CONTROL OF
NONCONFORMING
PRODUCT**

In the ideal factory, supplied material is always within specifications, all processes are fully capable and handling damage, product mix-up and other errors do not occur. While maintaining a goal to become the ideal factory or service provider, your company must be prepared to deal with nonconforming material or service errors.

The identification of known nonconforming product is the very first requirement. Capturing and securing the nonconforming material in a manner that denies unauthorized use, is also a requirement. These requirements, with associated responsibilities and authorities, must be detailed in a documented procedure. (8.3)

There are many actions that can take place with regard to nonconforming product discovered in your company. The fix may be as basic as sorting the good from the bad. It is sometimes possible to lower the grade of the bad product and use it in an application where it is acceptable. There may be opportunity to rework the nonconforming product and bring it back to conforming product. All of