

SAMPLE PAGES

FOR

ISO/TS 16949:2009
POCKET GUIDE

© Quality Pursuit, Inc.

**To order this pocket guide from
Quality Pursuit, Inc.**

call

1-800-278-7784

or

visit

www.qualitypursuit.com



Discussion of ISO 9001:2008 - 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 the above fulfill the need to take action to eliminate the nonconformity. Often the nonconforming product can be

MEASUREMENT, ANALYSIS AND IMPROVEMENT usable with the concurrence of the customer or a governing body. Repairing nonconforming product and bringing it to a usable state without achieving all specifications is also possible. Again, use could be allowed with the concurrence of the customer or a governing body. After repair or rework, re-inspection must follow. (8.3)

In the worst case, the nonconforming product might escape detection in your company and be delivered and used by the customer. The response in this case must be prompt and appropriate to eliminate or dilute the expected dissatisfaction. (8.3)

Discussion of TS 16949 Interpretations and Additions - TS 16949 immediately states that all of this subclause also applies to product suspected of being bad or product that is not identified. (8.3.1)

To avoid a cycle of problems, TS 16949 is asking that rework and reinspection be done using accessible instructions. The unavailability of these instructions to those doing the rework would be a departure from the requirement. (8.3.2)

If nonconforming product is inadvertently shipped to the customer, undelayed customer notification must occur. (8.3.3)

When the customer approves a product, service, or manufacturing process, the product/service must be provided as approved and the manufacturing process must behave as approved. In the event that this is not true, customer

MEASUREMENT, ANALYSIS AND IMPROVEMENT

approval must be secured. Tracking the use of the authorized quantity or assuring closure of the deviation on the predetermined date is also your company's responsibility. Similarly, your company must approve changes to supplied components/materials and your company's approval must have taken place before seeking the approval of the customer. Each container of deviated material must be marked to indicate so. When the deviation has expired, these temporary requirements must be replaced by the original requirements, new requirements, or extended if necessary. (8.3.4)

Management's Role - It almost goes without saying that management must first advocate the use of processes, techniques, etc. that contribute to the control and improvement of the process in order to minimize the size of your company's nonconforming material problem. Recognizing that there is, and will likely always be, some nonconforming material to deal with, management needs to be confident that the nonconforming material procedures prevent escape of nonconforming material. The nonconforming methods are linked very strongly to corrective and preventive action methods. Unexplainable escalating rates of customer complaints and nonconforming material provide hints to auditors that problems might not be receiving the appropriate treatments.

Each Employee's Role - The occurrence of nonconforming material can affect many different employees. The operator, where the problem occurred or the inspector, is usually first to become aware of its existence. When this happens, he/she must quickly take material out of the

system in accordance with the documented procedures.

Members of teams or committees, such as a Material Review Board, must carefully consider the dispositions and corrective actions.

Dispositions that are predetermined are often made right on the line and supported by the Nonconforming Material procedure. As an employee, you must be assured that you are authorized by your documentation to, for example, scrap a part that you think is not repairable.

There will be questions from the auditor about rework and reinspection instructions. He/she will also be very interested in situations where there were deviations from the specifications.

Auditors are always looking at the effort to segregate non-conforming product; the proper use of scrap containers; disposition of the nonconforming product; and for the evidence of follow-up inspection after repair and rework.



CLAUSE 8.4 ANALYSIS OF DATA

Discussion of ISO 9001:2008 - Data is being generated throughout the quality management system. Let's review as many as possible potential sources of data in a company's quality management system:

- training records
- training effectiveness measurements