

Corrective and Preventive Action... who needs it?

By David O. Weibel

Well, if you are an ISO 9000 Registered company, you need to have a program in place to meet the requirements of the Standard. If you are NOT registered to ISO 9000, it is simply Good Business Practice to have systems in place to correct recurring problems, and to prevent new problems from occurring. Customer satisfaction, cost savings and smoother operations should be the motivation.

What are Corrective and Preventive Actions?

The following definitions (underlined) are from the ANSI/ISO/ASQ 8402-1994 Vocabulary document.

Corrective Action

Action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence

Corrective Action involves fixing problems that *have already occurred* and may happen again (keywords above are “existing” and “recurrence”).

Preventive Action

Action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence.

Preventive Action involves looking for problems that have *not yet occurred* (keywords above are “potential” and “prevent”).

It should be clear to all that nonconformity, defects, and other undesirable situations cost money or poor performance in some or all of the following ways:

- Reduced customer satisfaction
- Late deliveries
- Inconsistent results
- Poor yields
- Poor quality
- Poor reliability
- Emergency overtime to fix problems
- Employee dissatisfaction

Thus it is financially positive to have systems in place to minimize these problems. What are the tools that we can use to reduce nonconformity? We can establish SYSTEMS and PROCESSES to lead us through the steps of the Corrective Action activity, namely:

1. Describe the problem or situation
2. Take short term actions as required to prevent further nonconformity
3. Determine the ROOT CAUSE
4. Develop and implement a long term solution to prevent recurrence of the nonconformity
5. Follow up to ensure that the solution was properly implemented and was effective

Let's expand on the above steps to give some specifics that you can use in your own problem situation. Note that in all of the steps, there should be a clear assignment of individual responsibility.

1. Describe the problem

Failure to properly describe the “problem” is a major problem in implementing a Corrective Action system. If the problem is not well documented in terms of WHAT, WHEN, and WHERE, there is little hope to be successful in finding the true ROOT CAUSE of the problem. A good rule of thumb is to describe the problem to the extent that you could duplicate the exact situation under which the problem originally occurred. Be specific and narrow in your description or definition of the problem. Determine the level of severity and urgency of the problem.

2. Take short term actions

Immediate action may be required to prevent known defective product or service from moving down the product stream. This may entail stopping production, sorting of output, extra supervision on services, immediate training, and other steps to prevent the continuation of the problem until the long term solution is put in place.

3. Determine the ROOT CAUSE

In most situations, there is a single root cause of the problem or nonconformance. This root cause may not be easy to find but there are numerous tools available to assist in finding “the” root cause. Later in this article there is additional information on methods and tools to determine the root cause.

4. Develop and implement a long term solution

Once the root cause is known (or presumed known) a solution must be developed which will remove the root cause of the problem. The development of the solution will usually involve testing of the solution in the environment that the problem originally occurred. Once the testing shows that the solution has a high likelihood of success, it should be implemented quickly.

5. Follow up

It is very important to follow up after the implementation to ensure that the solution was properly and completely implemented. Follow up should also focus on determining if the solution was effective in preventing a recurrence of the problem.

Any Corrective Action activities should involve a paper or electronic form to assist in collecting the description of the problem, and in keeping a living record of the current status of the Corrective Action.

Not all Corrective Actions need immediate attention, and some are more severe than others. Assigning categories and urgency allows you to work on the most important ones first.

Resources are normally limited in all businesses and it is important to work on the items that have the greatest impact on your organization. A log of the Corrective Actions showing dates opened, expected closures, assignment of responsibilities, and follow up activities is also important to assure proper management and closure of the problems.

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Message from GMP Labeling

We hope this newsletter includes information that you can use. Our goal is to periodically publish articles, written by quality professionals, that are timely and informative to the companies in our marketplace. Of course, along the way, we also hope to reinforce our image as a valuable resource to our customers.

Businesses regulated by the FDA and/or are ISO 9000 registered will find GMP Labeling products helpful in maintaining compliance. More than 5000 facilities in the U.S., Canada and Europe use the GMP Labeling System on a daily basis.

HACCP... Hazard Analysis and Critical Control Points

The FDA is considering Risk Management Inspections for the Medical Device Industry

By Jon L. Nickerson

Just when you have become comfortable with QSIT¹ (Quality Systems Inspections Technique) the FDA's Center for Devices and Radiological Health has developed a pilot program to determine if a Hazard Analysis and Critical Control Points (HACCP) protocol will result in more efficient and effective inspections.

HACCP was first required by the FDA for food processing for canned foods in 1973. More recently it has also become a requirement for processors of seafood, meat, and poultry. It has proved to be an effective process control strategy. Its application to the medical device industry is now being studied.

The FDA does not view HACCP as competition to QSIT, but rather as a complement. QSIT is a method of inspecting device manufacturers for compliance with the Quality System Regulation (21 CFR 820). It verifies that a viable quality system is in place and is being followed. HACCP inspections would be intended to verify that product risks (hazards) have been identified, and procedures are in place to control those risks. Preventing problems from occurring is the focus of any HACCP program.

Hazard Analysis is the process of collecting and evaluating information on hazards associated with the product under consideration, in order to decide

which hazards are significant. A Critical Control Point is a step in the manufacturing process at which control can be applied and is essential to prevent a deviation from the device specifications. The control for each such step includes establishing critical limits and monitoring to ensure the process stays within those limits.

HACCP also offers the possibility of more focused FDA inspections, reducing the time required to complete an inspection.

The regimen imposed by HACCP would likely result in better control of the manufacturing processes, which would likely result in manufacturing cost savings. It also offers the possibility of more focused FDA inspections, reducing the time required to complete an inspection. This is a powerful incentive for both the FDA and the device industry.

There are seven principles to the HACCP program:

1. Conduct Hazard Analysis and identify preventive measures.
2. Identify Critical Control Points.
3. Establish critical limits.
4. Monitor each Critical Control Point.
5. Establish corrective action to be taken when a critical limit deviation occurs.
6. Establish verification procedures.

7. Establish a record-keeping system.

A chart comparing these seven principles with the Quality System Regulation and ISO 9001/13485 is available on the FDA website. (Go to www.fda.gov and search for "HACCP Quality System Regulation.") The chart is reproduced at right.

Because the HACCP principles do not cover management responsibility or design controls, and are product specific, they cannot be considered a substitute for the Quality System Regulation. It may be practical, however, to use HACCP inspections in lieu of a full QSIT audit once a manufacturer has established a track record of compliance through successful QSIT audits. In addition, the product-specific nature of HACCP make it useful for PMA submissions. A shorter, more focused pre-approval inspection would result.

The FDA is working with several device manufacturers in a feasibility study to determine quantifiable, measurable data on the benefits and costs of establishing and maintaining an HACCP program. We should expect to see the results of this study within the next few months.

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1. GMP Labeling's Regulatory Compliance Newsletter, Fall 1999.

HACCP, Quality System Regulation, ISO 9001/13485 Comparison

HACCP Principle	Quality System Regulation	ISO 9001/13485
1. Conduct hazard analysis and identify preventive measures (Examples of preventive measures shown at right)	<ul style="list-style-type: none"> 820.30(g) – Design validation shall include... <i>risk analysis</i>, where appropriate 	<ul style="list-style-type: none"> 9001 4.4.8 Design validation 13485 4.4.1 General 13485 4.4.8 <i>Design validation</i>
	<ul style="list-style-type: none"> 820.70(a) – Where deviations from device specification could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe <i>any process controls necessary to ensure conformance to specifications</i>. 	<ul style="list-style-type: none"> 9001 4.9 (a)(c)(d)(e) and (f) process control
	<ul style="list-style-type: none"> 820.50 Purchasing controls 	<ul style="list-style-type: none"> 9001 4.6 Purchasing 9001 4.6.1 General
	<ul style="list-style-type: none"> 820.80 Receiving, in-process, and finished device acceptance 	<ul style="list-style-type: none"> 9001 4.10 Inspection and testing
	<ul style="list-style-type: none"> 820.86 – Acceptance status 	<ul style="list-style-type: none"> 9001 4.1.2 Inspection and test status
	<ul style="list-style-type: none"> 820.70(c) – Environmental controls 	<ul style="list-style-type: none"> 9001 4.9 (b) Process control 9001 4.11.2 (g) Control procedure 13485 4.9 (B) <i>Environmental control in manufacture</i>
	<ul style="list-style-type: none"> 820.70(d) Personnel 	<ul style="list-style-type: none"> 9001 4.9 (b) Process control 13485 4.9 (A) <i>Personnel</i>
	<ul style="list-style-type: none"> 820.70(e) – Contamination control 	<ul style="list-style-type: none"> 9001 4.9 (b) Process control 13485 4.9 (C) <i>Cleanliness of product</i>
	<ul style="list-style-type: none"> 820.70(g) – Equipment maintenance 	<ul style="list-style-type: none"> 9001 4.9 (b) and (g) Process control 13485 4.9 (D) <i>Maintenance</i>
<ul style="list-style-type: none"> 620.72 – Inspection, measuring and test equipment 	<ul style="list-style-type: none"> 9001 4.11 Control of inspection, measuring, and test equipment 	
2. Identify critical control points	<ul style="list-style-type: none"> 820.30(g) – Design validation shall include... <i>risk analysis</i>, where appropriate. 	<ul style="list-style-type: none"> 9001 4.4.8 Design validation 13485 4.4.1 General 13485 4.4.8 <i>Design validation</i>
	<ul style="list-style-type: none"> 820.70(a) – Where deviation from device specification could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe <i>any process controls necessary to ensure conformance to specifications</i>. 	<ul style="list-style-type: none"> 9001 4.9 (a)(c)(d)(e) and (f) Process control
3. Establish critical limits	<ul style="list-style-type: none"> 820.70(a) – Each manufacturer shall <i>develop</i>, conduct, control, and monitor <i>production processes</i> to ensure that a device conforms to its specifications. 	<ul style="list-style-type: none"> 9001 4.9 (a)(c)(d)(e) and (f) Process control
	<ul style="list-style-type: none"> 820.70(a) – Where process controls are needed they shall include: (2) Monitoring and control of process parameters and component and device characteristics during production. 	
4. Monitor each critical control point	<ul style="list-style-type: none"> 820.70(a) – Where process controls are needed they shall include: (2) <i>Monitoring</i> and control of <i>process parameters and component and device characteristics</i> during production. 	<ul style="list-style-type: none"> 9001 4.9 (a)(c)(d)(e) and (f) Process control
5. Establish corrective action to be taken when deviation occurs	<ul style="list-style-type: none"> 820.100(a) – Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (3) <i>Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems</i>. 	<ul style="list-style-type: none"> 9001 4.14 Corrective and preventive action 13485 4.14 <i>Corrective and preventive action</i>
6. Establish verification procedures	<ul style="list-style-type: none"> 820.80 – Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other <i>verification activities</i>. 	<ul style="list-style-type: none"> 9001 4.10 Inspection and testing
	<ul style="list-style-type: none"> 820.100(a) – Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for (4) <i>Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device</i>. 	<ul style="list-style-type: none"> 9001 4.14 Corrective and preventive action 13485 4.14 <i>Corrective and preventive action</i>
7. Establish record-keeping system	<ul style="list-style-type: none"> 820.70(a) – Where process controls are needed they shall include: (1) <i>Documented instructions, standard operating procedures (SOPs) and methods</i> that define and control the manner of production; 	<ul style="list-style-type: none"> 9001 4.9 (a)(c)(d)(e) and (f) Process control
	<ul style="list-style-type: none"> 820.100(b) – <i>All activities required under this section, and their results, shall be documented</i>. 	<ul style="list-style-type: none"> 9001 4.16 Control of quality records
	<ul style="list-style-type: none"> 820.181 – Device master record 	<ul style="list-style-type: none"> 9001 4.2.2 Quality-system procedures 13485 4.2.3 Quality planning
	<ul style="list-style-type: none"> 820.184 – Device history record 	<ul style="list-style-type: none"> 9001 4.16 Control of quality records 13485 4.16 <i>Control of quality records</i>
	<ul style="list-style-type: none"> 820.186 – Quality system record 	<ul style="list-style-type: none"> 9001 4.16 Control of quality records 9001 4.4.2 Quality-system procedures

Where do Corrective Actions come from?

Customer complaints: All customer complaints should be reviewed for possible Corrective Action activities. Not all cases will warrant action, but some will definitely qualify.

Rejected Materials: These should be documented and reviewed to establish severity and urgency. There may be situations where the level of severity does not require a Corrective Action.

In house system failures: When there are breakdowns in internal operating systems or procedures, they should be documented and reviewed for impact on operations. Paperwork errors, errors in order taking, shipping activities and other related items may need Corrective Action.

Schedule delays: Schedule delays may indicate a “problem” that needs some type of corrective action to bring things back on schedule. Failure to meet a schedule indicates a failure to meet a plan, and thus a nonconformance.

Supplier Problems: Incorrect, late or poor product quality deliveries of items from suppliers is a major source of problems in many companies. (Inadequate requirements information from the purchasing company is a prime root cause.)

Audit Results: If you have an Internal Audit function, this group will be finding problems and nonconformances as a part of their audits. If you do not have such a function, employee suggestion systems and workplace complaints indicate problems needing Corrective Action.

Software Bug Tracking: Software bugs are a source of information for the Corrective Action system. In most companies software bugs are handled in a separate system but the steps in arriving at a solution are similar.

This is certainly not all of the sources for nonconformances, but will give you an idea of the types of sources.

What is this “ROOT CAUSE” thing?

Root Cause is defined as “*The fundamental underlying cause of a defect, deviation, or nonconformance. Removal of this cause will eliminate the nonconformance.*” (Definition per the “8402 Vocabulary” document above).

In MOST cases, there will be a single root cause that can be determined. A good test to see if it is indeed the root cause, is to establish conditions that will allow the root cause to be introduced into the situation and then taken away. Kind of turning it on and off to see if indeed it is the root cause you are looking for.

How do I find the “ROOT CAUSE” of my problem?

Finding the root cause of a problem or nonconformance is not always easy. If the initial description of the problem is not clear and complete, it may not be possible. In most cases however, there are several tools that can be helpful.

Collection of more data regarding the problem may be required. Before you embark on a massive data collection process, take time to think what information will be useful. Taking too much data can be costly in terms of effort and time. Plan on how you will present the data to help you understand the problem.

Is the problem a “variables” problem, i.e. the dimension of a part is consistently over the tolerance, or is it an “attributes” problem, i.e. an item is consistently left out of the shipping package.

Variables problems can make good use of various statistical tools such as X-bar/R and histogram charting, while attributes problems may better make use of things such as flow and fishbone dia-

grams. Another good method is to keep asking the question “WHY” (did this happen) until you arrive at the foundational or root cause. Usually you will be able to arrive at the root cause within about 5 levels of “WHY” questions.

“Brainstorming” is a very good beginning tool to collect information from other individuals who may have information that is helpful in determining the root cause. Results of a good brainstorming session can narrow down and direct the search for the root cause. Involve the people in the immediate area of the problem and get their ideas.

What is PREVENTIVE ACTION?

It is always better to prevent a problem from happening than to fix an existing problem. Therefore, it makes great sense to develop a system to get out in front of “problems” and prevent them from occurring. How can we do that? Here are some potential areas to explore in performing Preventive Actions:

- Data and trend analysis for all “key” characteristics
- Review of prior problems
- Documentation of Procedures and Processes (including job descriptions)
- Training on Job Requirements
- Establish feedback on job performance for all individuals

The subject of Preventive Action gets too little attention in management today. If you would like us to present another article focusing on this subject in a future issue, please so indicate on the enclosed reply card.

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