

Preventive Action ... it makes good \$en\$e

By David O. Weibel

Preventive Action is a logical and financially rewarding extension of any program that is oriented towards correcting existing problems. In a previous article¹ on Corrective and Preventive Action, we outlined the activities that are beneficial if not necessary for a Corrective Action Program. In this article we give some ideas on how to take it to the next logical step, which is to prevent problems before they happen.

In the previous article, we referenced the definitions of Corrective Action and Preventive Action which come from the ISO Standard ANSI/ISO/ASQ 8402-1994 Vocabulary document.

Corrective Action involves fixing problems that *have already occurred* and may happen again.

Preventive Action involves looking for problems that *have not yet occurred*.

Why is Preventive Action important to an organization? If implemented well, it can do the following for the organization:

- save money,
- improve customer satisfaction,
- improve employee morale, and ...

If this activity has all these benefits, why are we not doing it already? Well, in many cases you are but have not clearly identified it and focused on specific goals for improvement.

Some of the things that you or your organization may already be doing that are Preventive in nature are:

- training,
- documenting your processes,
- giving feedback to employees on good performance and areas for improvement,
- setting performance goals.

Now we have established that many of you are already doing some things in this important area, what about stepping up the level, to gain more advantage? It is not as difficult as you may think, if you break it down into areas that need, or may need, attention. Let's consider that we may have issues to deal with in the following three areas:

1. **Cultural** issues
2. **People** issues
3. **Tool** issues

If we break these areas down into bite-size pieces, set goals, assign responsibil-

ity, and then measure results for these small pieces we can make significant progress.

Most of the written material on Preventive Action is focused on the Tools available to implement a Preventive Action program. Below we will discuss two important precursors to a successful implementation, namely, Cultural issues and People issues.

Cultural issues

What is the culture of your business or organization? (These principles apply equally well to nonprofit groups and service activities, as well as "traditional" manufacturing.) Whether you realize it or not, your organization has a culture. It may not be documented or formally recognized, but it exists.

A first step on the road to improvement is to identify your company's culture, and then see if it can be enhanced to include a strong(er) commitment to improvement.

Successful companies have a culture that (as a minimum) has elements that focus on satisfying their customers (stakeholders), continually improving operations, and a long-term commitment to their employees. There may be many additional elements in their culture but we will focus on the *continuous improvement* aspect here.

Establishing a culture for continuous improvement is a positive step in improving operations. A commitment to continuous improvement is the foundation for a Preventive Action program. To implement such a cultural change requires that specific measurable goals be clearly documented, communicated to all staff, and positive behavior rewarded.

This cultural change is the responsibility of management and the management team must take an active, continuous, and positive role in it.

The specific action that must be taken is to establish measurable goals in a number of areas. This would include things such as reducing the number of customer complaints, reducing scrap and rework costs, improvements in serviceability/maintainability of products and other specific operational parameters.

People issues

Once the cultural foundation has been established, the people in the organization must implement it. How do they do this? They must understand the cultural goals, feel motivated to implement them, and have the necessary resources and tools to allow them to meet the goals.

Motivation and empowerment are vital to success for the people implementing a Preventive Action plan. The people who are involved with Preventive Action activities must feel that there is a strong need to improve things. They must feel that they have the power to change things within a defined system. They must feel that there is some benefit to them for implementing the changes. These benefits may be but are *not* required to be financial in nature. Most people do not like to see waste or inefficiency in their jobs and will offer ideas and suggestions as long as they feel that someone is listening to them.

One thing, then, that can be done to *prevent* problems is to listen to the people who are directly involved in the work activity. If their ideas for improvement are accepted, give them recognition for their efforts. Financial rewards are helpful, but a simple personal and direct *thank you* goes a long way to motivating an individual to come back with more suggestions.

Much is written about "empowerment" and I will not add anything new to the body of literature here. It is important that people at the front line are given the

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 GMP Labeling products on a daily basis.

power, along with the knowledge and tools, to make decisions that will prevent problems. If they are making incorrect decisions in preventing problems, then they should receive additional training on how to do better.

People issues are also a management responsibility. Management must set the goals, and then provide the tools for the people to use.

Tool issues

Now we can get to some concrete “hard” topics after we have addressed the above “soft” topic issues. Here are some tools to help us implement a Preventive Action program.

- Establish a “system” to encourage, document, follow up on, and provide recognition for preventive actions.
- Establish a “Continuous Improvement” program, building on the “system” established above.
- Measure and control the various “Costs of Quality.”
- Establish strong design control practices for new products, including such items as Failure Mode and Effects Analysis (FMEA).
- Utilize “Process Capability” tools.
- Use some of the problem solving “Tools of Quality” such as:
 - Brainstorming
 - Fishbone/Cause & Effect Diagrams
 - Flowcharts
 - Control Charts, Histograms, and Pareto Charts

Establish a system

A successful Preventive Action program will establish a “system” or methodology for encouraging, documenting, following up on, implementing and rewarding Preventive Action ideas.

The first step is to create an environment that encourages individuals to be active in preventing problems. Communicate clearly the objectives, expectations, and boundaries of the Preventive Action program in written form.

Next, provide forms or other means to

document the ideas, set up a focal point (person/department) for them to be forwarded to, and a means of logging them in and making the status visible to all.

Resources MUST be provided to evaluate the ideas, and assess their feasibility and desirability. This must be done in a timely manner, and clear feedback given to the person submitting the idea. Many Preventive Action systems fail because ideas are not thoroughly evaluated and feedback is not given to those submitting them.

If the idea merits some action, then implement the action(s) and publicize the potential or actual benefits.

Some form of reward or at least personal recognition is crucial for the program to be successful. Many times a simple “thank you” will be sufficient, but if significant savings are the result, then some form of financial reward should be made. Successful ideas should be broadly communicated both as a means of recognition, and as a stimulus for others to generate their own ideas.

Continuous improvement

If the fundamentals described above are in place, then a possible next step is to strive for “Continuous Improvement.” This involves establishing goals and objectives that are measurable. To continually improve implies that you know where you were, and where you are now.

A Continuous Improvement program can be global or local in nature. Corporate wide Continuous Improvement goals are often difficult to implement until there is some experience with a local or more limited scope program. The system to measure the improvement MUST be in place prior to the kickoff of the program so that the baseline of performance is known.

Improvement goals must be quantitative (measurable), have a time duration, and be made visible to all participants in the program. Goals such as “Improve on-time delivery” are not good goals. A goal to “Improve on-time delivery from the current level of 96% to at least 98% by July 1, 2001 is a measurable, time

dependent, and viable goal. There are many good books on the subject of Continuous Improvement available from the ASQ Press² and other sources.

The costs of quality

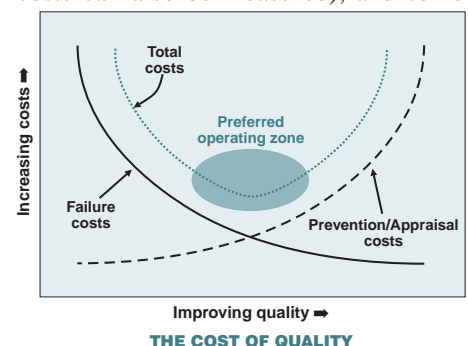
“Quality is Free” is the title of a very popular book by Philip B. Crosby in the past; the book proposed that indeed one could reduce costs by improving quality. I heartily agree, but this implies that one knows the various cost elements of quality and can make effective decisions to optimize the various elements to bring costs to a minimum. There are several elements of Quality Costs (or the cost of NON quality):

Failure costs (internal and external): these costs include warranty, loss of customer confidence, scrap and rework costs.

Prevention costs: these costs typically include the costs of operating the Quality Department, training, costs of a Preventive Action program and other costs which result from efforts to “prevent” failure.

Appraisal costs: these costs normally include the cost of inspection activities at various stages of the product/service delivery process.

The graphic below indicates that as the level of Quality improves, Failure costs decrease, and Prevention and Appraisal costs may go up. The total of these costs is the Total Quality Cost and there is a “sweet spot” where these costs can be minimized. Note that some of these costs are easy to measure (Quality Department costs can be determined from budgets, internal scrap and external warranty costs can also be measured), and some



are not so easy to determine, such as the loss of customer confidence.

To use this tool you need to make some rough estimates of these costs and recognize that this is an inexact process. The primary benefit of doing a Quality Cost analysis is most likely to determine, in gross terms, where on the curve you are operating and to assist in making decisions as to where you want to be in relation to the “Preferred operating zone.”

From the graphic you can see that increasing prevention and appraisal costs will reduce failure costs. You should also recognize that, in general, a dollar spent on Prevention is a better investment than one spent on appraisal/inspection.

Failure Mode and Effects Analysis

The source of many quality problems can be related back to the original development of the product or service. Note that the Preventive Action process applies to services as well as products.

Pioneered by the automotive industry, FMEA has been accepted by and is frequently a requirement in the medical device industry. FMEA is a very valuable tool to use in preventing quality problems. During the design/development stage of a product or service, a structured multi-disciplined approach is taken to evaluate ALL potential failure modes of the product/service and to determine the potential effects of the individual failure. Failure causes and the potential effects are analyzed and prioritized to minimize negative consequences *from the customer point of view*. Note that “customer” is not limited to the end user; it should include subsequent operations in a multi-step process.

FMEA may also determine process variables from a manufacturing or delivery process that need to be controlled using the process capability tools mentioned later in this article. General information on FMEA is available from the FMEA Information Center³; FMEA information for the medical device industry is available through the Assoc. for the Advancement of Medical Instrumentation⁴. The American Society for Quality (ASQ)² also has information on FMEA.

Quality Planning

Quality Planning in relation to new products is another tool which may be used in a Preventive Action program. Quality Plans are a part of the new ISO 9001-2000 under element 7.1 “Planning of product realization.” Planning should include setting Quality Objectives and Requirements for the new product or service, and establishment of required

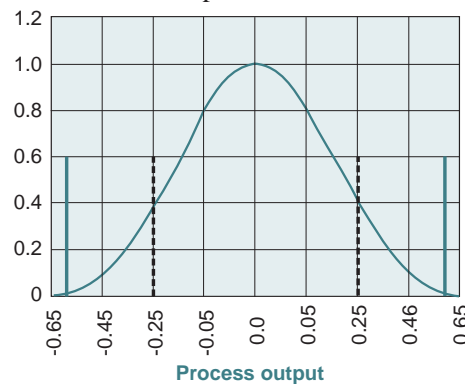
verification, validation, monitoring, inspection and test activities.

Process Capability

Process Capability is a Preventive Action tool used in Process Validation. While it can be applied to both “hard” and “soft” processes, it is used mostly with hard processes such as machining, chemical, or similar quantifiable processes, and to a lesser degree with so-called “soft” processes such as customer services.

Basically, we are seeking to determine if the process used to deliver the goods/service is capable of producing the item within the requirements/specifications on a consistent basis.

Consider the graphic below, which shows the output of some process such as a machining process. The “normal” distribution of the output of the process indicates that almost all of the results of the process will be between the normalized values of -0.60 to $+0.60$. Thus, if the acceptable specification limits of the process are between -1 and $+1$, the process would be considered Capable.



If, however, the acceptable limits (tolerances) are set at ± 0.25 , much of the output of the process is going to fall outside the specification limits and the Process would NOT be considered capable of meeting the specification requirements. While we don't have space to go into the mathematics here, basically, a process capability index C_{pk} is calculated to determine the extent to which the process is capable

Why look at this information? If there is a LOW process capability, you can be assured of problems and defects. If you can improve the capability of the process, you have removed the potential for problems and thus performed a Preventive Action.

Problem solving tools

There are a number of straightforward easy-to-use “tools” that are helpful in a Preventive Action program:

- Brainstorming
- Cause/effects diagram

- Flow diagrams
- Control “x bar and r” (\bar{x} , r) charts
- Histograms
- Pareto charts

Brainstorming: A great tool for the collection of team ideas. Get the group together and write down (visible to all) the problem statement or topic you want to brainstorm. Record all of the ideas and thoughts generated *without comment or criticism*.

Unstructured brainstorming takes ideas from anyone at any time. Structured brainstorming goes around the room in a fixed sequence. Either method is OK, just be sure to capture ALL contributions. After a flurry of ideas, there will be a lull, and then with some encouragement, a second round of ideas. Usually when this second round of ideas dies down, you have captured most of the ideas that are going to come out.

Now you can go back and clarify, categorize, or combine the ideas into a more useful format. Avoid criticism as this will inhibit ideas at future sessions.

Cause/Effect Diagrams: (also known as Fishbone/Ishikawa diagrams) are useful to determine root causes for problems, to assure that the solution proposed really fixes the initial problem and prevents its recurrence.

In a group or team setting, make an initial statement of the problem you wish to understand. The quality of the result will be directly proportional to the quality of the initial problem statement, so take time to clearly state the problem.

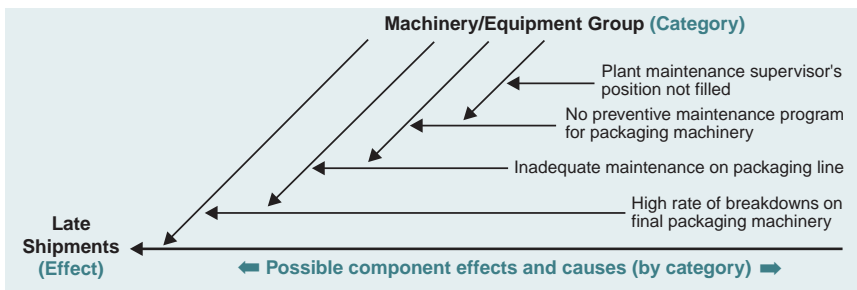
A simple diagram is shown on the next page. The process begins with a good problem statement such as: “Shipments from the factory are late (past the promised date) more than 30% of the time.”

This is the **Effect** and we are trying to find the **Cause**. Next you would begin to list on the diagram the possible causes in each of the categories that pertain to your situation. For example, one possible cause under the Machinery/Equipment category would be High rate of breakdowns on the final packaging machinery.

One could then use that as an effect and ask what is the cause of the high rate of breakdowns. The answer might be inadequate maintenance activity on the packaging line.

The next step would be to determine the cause of inadequate maintenance. That might be lack of an organized preventive maintenance program for packaging machinery.

The reason for this might be Plant



Maintenance Supervisor's Position not filled (open requisition).

As each cause is identified, it becomes an effect to be analyzed for the proper cause for it. This continues for about 4–5 levels of cause and effect if possible. The resulting pattern of Causes will probably converge on the true “Root Cause” of the problem statement you started with. Many times the same root cause will emerge from several of the categories. When this happens, it is strong evidence that the common message is indeed the root cause of the problem statement.

Flow Diagrams are a good tool to analyze your current operations and understand all the interactions and interdependencies. A valuable way to use flow charts in a Preventive Action situation is to do an “As Is” flow chart, then look at it for activities and elements that **do not add value and may create confusion/problems.**

Are there activities that have crept into your business operations that are outmoded and do not add anything to help you accomplish an end goal or objective? Many such activities may exist and a flow chart makes them more visible. Once you have analyzed the “As Is” chart, then and only then, should you make changes and develop the “Should Be” flow chart. You can design OUT the non-value-added items and those that are causing confusion and quality problems. Start the dia-

gram with a small segment of the activity and add other activities when the initial area has been fully documented.

Control Charts: There are many types of control charts that can be used, but the simplest and a very common type of chart tool used in Preventive Action is the \bar{x} , r chart for Variables Data. This chart shows whether a process is stable or its centerline and range of variables are changing.

These factors are all important in understanding if adjustments to a process are required to prevent it from going out of control. If the process average is changing, moving up or down, then more of the output will no doubt be outside of the tolerance limits. Similarly, if the range of the process widens, again more of the output may be outside the limits. \bar{x} , r charts are a simple beginning step to performing the Process Capability activities discussed above.

Histograms are useful along with the control charts discussed above to give a visual picture of distribution of outcomes of the variables data. Many people are familiar with what is called the “normal” distribution or the bell-shaped curve. This curve shows where the mean or average is and what the range of the outcomes are. This information also tells visually what the relationship of the process is with regard to the acceptable limits. Non “normal” curves give various indications about the process that may be

useful in controlling it.

Pareto charts are a tool to help determine which are the most frequent or KEY problems. Generally, solving these most frequent problems will generate the most reward. The Pareto Principle is that 20% of the sources cause 80% of any problem.

The Pareto chart is used with “attributes” data as opposed to variables data. Attributes data is usually not numeric, but may be categories of defects such as poor surface finish, off-color, wrong material used, etc. The first step is to determine the problem you wish to better understand (brainstorming is a good tool to do this), then record the attribute defect data as it occurs on a check sheet for the time period already determined.

A Pareto chart is simply a bar chart representation which shows the most common defects first, then the second most common, and so on down the line. Working on the most common defect or problem is often a way to get the most from your efforts in the shortest period of time. When the most common one is solved, working on the next will yield the next greatest reward and so on.

Available tool guides

Help with many of the above tools can be found in the form of inexpensive pocket guides and other training materials available from Goal/QPC⁵. The “Memory Jogger II” contains information on Process Capability, Brainstorming, Cause and Effect Diagrams, Control Charts, Histograms, Pareto Charts, and many other very useful tools.

Dave Weibel is a RAB Registered Lead Auditor (Q02444) and provides consulting services related to quality management. Mr. Weibel can be reached at daveweibel@home.com.

5. www.goalqpc.com/

GMP Labeling® , Inc.

525 West Remington Drive
Sunnyvale, CA 94087

Phone **800-637-4487**
408-522-3200
Fax 408-522-3212
E-mail sales@gmplabeling.com
Web www.gmplabeling.com

Fax to 408-522-3212
to be added to our mailing list
for future issues of this
Regulatory Compliance Newsletter

Bulk Rate
U.S. Postage
PAID
San Jose, CA
Permit No. 125