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*A flexible approach to business improvement*

- ***Why organisations have not gained the benefits***
- ***The real purpose for Corrective Action***
- ***The real purpose for Preventive Action***
- ***An effective approach to Preventive Action***
- ***An effective approach to Corrective Action***

# UNDERTAKING EFFECTIVE CORRECTIVE AND PREVENTIVE ACTION

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# Clearing up the misunderstanding

After 30 years during which the terms corrective action and preventive action have been used in the specification of management system requirements, there remains as much confusion as when the terms were first introduced.

### Is fixing the problem really corrective action?

The term corrective action is often believed to be about fixing problems and preventive action about preventing recurrence of problems. Corrective Action is also a commonly used term for an action that puts things right, removes the defect or rectifies mistakes. This is understandable because synonyms for correction are fix, remedy, rectify and alter. But corrective action in ISO 9000 and its predecessors has always been about preventing recurrence because *nonconformity control* addressed the correction of problems. There is a view that 'control of nonconforming product' is about containing the offending item, identifying and segregating it so as to prevent it being processed, installed or delivered. But there is another part to the requirement – a part that deals with the 'disposition' ie deciding what to do with the nonconforming product and it is this decision and subsequent action that removes the nonconformity, fixes the problem or rectifies the mistake. The term used in ISO 9000 for correcting the nonconformity is *correction* - which is a little too similar to the term *corrective action* to avoid confusion. A better term would be Remedial action.

### Is preventing recurrence really preventive action?

The joining of the two terms in the phrase 'corrective and preventive action' compounds the misunderstanding because it seems like it should be about correcting problems and preventing their recurrence. On the contrary it is about preventing the recurrence and preventing the occurrence of nonconformities. A problem has to exist for corrective action to be taken. Therefore one simply cannot take both a corrective action and a preventive action on the same problem. One can either stop the problem recurring or stop it occurring. When actual problems don't exist but there is a possibility they could occur, the action of preventing the occurrence of the problem is a preventive action.

### Are the auditors to blame?

It is therefore not surprising that we have such documents as Corrective and Preventive Action Procedures that contain forms with provision for describing the Corrective Action (presumably to correct the nonconformity) as well as provision for describing the Preventive Action (presumably to prevent the nonconformity recurring). The survival of these forms through the last two decades, in spite of frequent audits by accredited certification bodies, either suggests that the auditors are ignorant or that they have turned a blind eye. Perhaps they have been persuaded that preventing a problem occurring in another area, another process or in another product is preventive action and therefore there was no need for any further type of action. This notion would seem to be supported by the countless requests for Corrective Action from Auditors following an audit. Do they mean Corrective Action or do they mean Remedial Action? Because they appear to be satisfied when their Client merely fixes the problem by changing a procedure that should have been correct in the first place. They seldom question the competence of those writing and approving the procedure.

### Just because its not happened here doesn't mean it's a case for preventive action

So the idea that preventing a problem identified in one area/product/process from occurring in another area/product/process is a preventive action rather than a corrective action gains credibility because the problem has not yet occurred in the other area/product/process. However, if the cause of the existing problem has been truly eliminated, it will neither recur in the same area/product/process or any other area/product/process within the same organization. This is an issue of getting to the root cause. Often the search for the root cause is limited to the nonconforming product. Changing the product design is believed to eliminate the root cause. The nonconformity should not recur in that specific product again but unless the process design is changed it might recur with other products. Sometimes, changes are made to procedures in the hope that the problem does not recur but procedures are not

processes. If the same personnel are employed and not retrained or the same techniques, technologies, equipment as caused the original problem, it will undoubtedly recur.

It might be felt that, after a period of time taking corrective action of the type described above, and eliminating the real root cause, there will be no possibility of ever again detecting nonconformity. If the status quo remained into infinity this would be true, but as with death and taxes, change is another certainty in life. There are always changes, changes in the environment, customers, stakeholder expectations, technology and change throws up new challenges for which existing solutions might be inadequate. It is here that the product and process designer must examine the probability of failure, discover the failure mechanisms and their root cause and prevent their occurrence. The solutions found may be new to the organization but not necessarily new to other organizations. So let us recap.

### Remedial action

*Remedial action* is action proposed or taken to remove nonconformity. Product recall is a remedial action not a corrective action; resolving a customer complaint is a remedial action not a corrective action; correcting a nonconformity detected by an internal or external auditor is a remedial action, repair, rework, return to supplier for a replacement are all remedial actions because in all of these cases the action does not prevent a recurrence of the problem.

### Corrective action

*Corrective action* is action planned or taken to stop something from recurring anywhere and on anything in the organization. It could be a one-off event (special cause variation), a recurring event or an inherent condition (common cause variation). Action taken to prevent a problem recurring in another area, product or process that has the same root cause is a corrective action. Action taken to contain a nonconformity, ie, stop it spreading or recurring while the root cause is eliminated is a *remedial action* even though it might be perceived as a corrective or preventive action. It may be termed a *Containment Action* to distinguish it from action on an actual nonconformity.

### Preventive action

*Preventive action* is action proposed or taken to stop something from occurring anywhere and on anything in the organization. When actual problems do not exist but there is a possibility of failure, problem or error, however unlikely, the action of preventing the occurrence of this failure, problem or error is a *preventive action.* Preventive action may therefore follow an analysis of risks and an assessment of the impact of those risks.

## Undertaking corrective action

### Scope of action

Corrective action is the pattern of activities that traces the symptoms of a problem to its cause, produces solutions for preventing the recurrence of the problem in any existing area, product or process in which it might occur, implements the change and monitors that the change has been successful.

One needs traceability to find the root cause of a problem and take corrective action to prevent its recurrence. It is for this reason that records are maintained that identify and describe the product/process that might be susceptible to failure

### Process variation

Where nonconformity reports have provision for fixing the problem and taking corrective action there is a presumption that corrective action should be taken for every incident of nonconformity but such action does not apply in every case.

There is variation in all processes. Where a process is under control it may produce nonconformity because it is not a capable process. Action to correct the nonconformity is Remedial Action. Whether or not action should also be taken to prevent recurrence depends upon the objectives for the process and the measures used to determine its performance.

A process may be designed so that it produces no less than 99.73% conforming product (ie 3 sigma or no more than 27 nonconformities/Ten thousand products). When the first

nonconformity occurs, remedial action is taken but not corrective action because the process performance standards are being met. Nonconformities can continue to occur without corrective action being necessary up to the 27th nonconformity in a population of 10 thousand products. When the next nonconformity occurs in the same population ie the 28th, corrective action is now necessary because process performance has fallen below standard.

What this means is that variation is normal – it is a characteristic of all processes. It is like death and taxes – inevitable. When the variation is within the prescribed limits, no corrective action is needed – in fact it might cause instability in the process. However, in reality, organizations have not defined performance standards for their processes resulting in a perception that any variation is intolerable and must be eliminated.

### ISO 9001:2000 requirement

ISO 9001:2000 clause 8.2.3 requires process monitoring and measurement and states "When planned results have not been achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. Now we have a better understanding of *corrective action* we can interpret this requirement more concisely.

It is saying that when a process produces nonconforming product we must correct it and when the process fails to achieve its performance standard we must take corrective action but not every time the process produces a nonconforming product.

### Application of corrective action

Steps in the corrective action process are as follows:

1) Set performance standards for each process
2) Monitor process performance
3) Collect the nonconformity data and classify
4) Conduct a Pareto analysis to identify the vital few and trivial many
5) Organize a Diagnostic Team for the vital few
6) Postulate causes and test theories
7) Determine the root cause of nonconformity
8) Determine the effects of nonconformity and the need for action
9) Record the criteria for determining severity or priority
10) Determine the action needed to prevent nonconformity recurring
11) Organize an Implementation Team
12) Create or choose the conditions that will ensure effective implementation
13) Implement the agreed action
14) Assess and record the actions taken and record the results
15) Determine whether the actions were those required to be taken
16) Determine whether the actions were performed in the best possible way
17) Determine whether the nonconformity has recurred
18) If nonconformity has recurred repeat steps 1 to 17.

### Reporting form title

A problem is commonly perceived to be any situation in which the results achieved were not those that were expected. When a process is producing nonconformity but the level of nonconformity is not above what we might expect from the process, there is no problem. Remedial Action takes care of it. When the level of nonconformity rises above what we expect there is a problem and therefore an appropriate label for the report we use to collect and transmit information about a problem would be a Problem Report rather than a Corrective Action Report. The label Corrective Action Report will send out the wrong signals because of the misunderstandings we have referred to in the this paper.

# PROBLEM REPORT

## IDENTITY

| What's it about? | | **PR/** |
|---|---|---|
| Where was it found? | Who found it? | When: |

## VARIATION

| | |
|---|---|
| | 1. What is nonconforming?<br>2. Why is it a problem?<br>3. Where is the criteria stated? |
| Problem Owner Date: | |

## ROOT CAUSE ANALYSIS

| | |
|---|---|
| PIF Date: | 1. What was happening at the time?<br>2. What was being done prior to the incident?<br>3. What is the root cause? |

## CORRECTIVE ACTION

| Plan | Action Date | Actionee | Date Complete | |
|---|---|---|---|---|
| | | | | 1. Changes to design standards<br>2. Changes to process design<br>3. Changes to resource levels<br>4. Training<br>5. Changes to objectives & targets |
| PIF Date: | | | | |

## EFFECTIVENESS OF ACTIONS

| All actions taken and effective Yes ☐ No ☐ | Reviewed by: | Related PRs | Date Closed: |
|---|---|---|---|

# Undertaking preventive action

## Scope of action

Preventive action is the pattern of activities that identifies potential problems, traces the symptoms to their cause, predicts the probability of occurrence, produces solutions for preventing occurrence, implements these solutions and monitors their effectiveness.

This action is very much different to corrective action as it is more cerebral, intuitive and imaginative. The process is triggered by questions such as “What could go wrong? What happens if? How might this fail? The answers always come from past experiences, which is why it is a practical technique and not a theoretical one. A house roof is designed to withstand forces that can be expected to apply over its lifetime. Such forces would include those due to wind, rain, snow and people. It would not be designed to withstand a falling tree or an aircraft falling from the sky because the probability of these events is very low, probably once in a million years whereas, rain, wind and snow are daily or at least yearly events. While an event may have a probability of occurrence of once in 100 years, when it does happen, the consequences might be so great as to destroy the town. Preventive action of some kind may therefore be not unreasonable. What would be unreasonable is to take action to prevent an event that is highly unlikely to occur during the life of the product, the person, the organization, the community etc. Preventive action is therefore about risk assessment.

## Application of preventive action

The most cost effective action one can take in any organization is an action designed to prevent problems from occurring. Preventive action therefore saves money even though there is a price to pay for the discovery of potential nonconformities. The process though which potential nonconformities are discovered is a risk analysis and assessment process

The action necessary to eliminate, reduce or control the effects of a potential nonconformity may be as simple as applying existing techniques or methods to a new product or process. In other cases it might involve designing new techniques and methods – something that may require additional resources and a development team.

Steps in the preventive action process are as follows:

1) Determine the objectives of the product, process, task or activity.
2) Organize a Diagnostic Team.
3) Perform an analysis to determine the factors critical to the achievement of these objectives.
4) Determine how the factors might act to adversely affect the product, process, task or activity (the mode of failure).
5) Determine the potential effect of such condition on the achievement of the objectives.
6) Record the criteria for determining severity or priority.
7) Determine the severity of the effect on meeting the objective.
8) Assess the probability of this condition occurring
9) Postulate causes and test theories.
10) Determine the root cause of potential nonconformity.
11) Identify the provisions currently in place that will prevent this adverse condition occurring or detect it before it has a detrimental effect on performance.
12) Assess the probability that these provisions will prevent this condition occurring or detect it before it has a detrimental effect on performance.
13) Determine any additional action needed to prevent the potential nonconformity occurring.
14) Organize an Implementation Team.
15) Create or choose the conditions that will ensure effective implementation.

16) Implement the agreed action.
17) Determine whether the actions were those required to be taken.
18) Determine whether the actions were performed in the best possible way.
19) Determine whether nonconformity has occurred.
20) If nonconformity has occurred undertake corrective action and review the preventive action methods.

It is necessary when considering the requirements for preventive action to avoid limiting your imagination to products. There is likely to be a greater potential for failure in the organization and its processes as in its products.

## Analysis forms

This is an example of a risk assessment on a Mission Management Process.

*Process purpose*: Determines the direction of the business, continually confirms that the business is proceeding in the right direction and makes course corrections to keep the business focussed on its mission.

| Risk/Failure Mode/Hazard | Effect | Cause | Probability | Controls |
|---|---|---|---|---|
| Failure to recognize a change in customer expectations | Decline in business prospects | Not getting close to the customer | Currently low due to MD handling all new business | Quarterly review |
| | | Ignoring customer feedback | Currently low due to MD handling most customer contact | Feedback log |
| Failing to focus on the right priorities | Stakeholder dissatisfaction | Ineffective communication of strategy | Currently low due to small number of staff | Quarterly review |
| Pricing ourselves out of the market | Lose business | Taking too much profit | Low | Annual competitive analysis |
| | | Paying too high wages | Low | |
| Loss of records | Cannot determine performance in the short term and demonstrate effectiveness in the long term | Inadequate filing system<br>Poor security<br>Computer hard disc failure<br>Premature disposal | High | Computer hard drive back-up for digital data<br>Archive store for hard copy<br>Disposal log to record disposal actions |