CORRECTIVE ACTION - ITS CORRECT UNDRSTANDING AND IMPLEMENTATION

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1. INTRODUCTION

Quality is the watchword for all activities today and a quality management system is necessary for sustenance of quality. The effectiveness of the quality system, however, can be directly correlated to the effectiveness of its built-in system of corrective actions. This important tool provides the mechanism for correcting the quality problems of process, product and services of an organization so that the quality system continues to be effective. The organization could be a manufacturing company, an organization providing any type of service or a testing or a calibration laboratory.

This paper examines the fundamentals of the different stages of a corrective action and discusses ways of correctly implementing the same for the benefit of all concerned.

2. CORRECTION & CORRECTIVE ACTION

By definition, Correction is “Action to eliminate a detected nonconformity”. Corrective action, on the other hand, is “Action to eliminate the cause of a detected nonconformity or other undesirable situation” and nonconformity is “Non-fulfillment of a specified requirement”. In order to apply a corrective action, therefore, the cause of the nonconformity should first be determined.

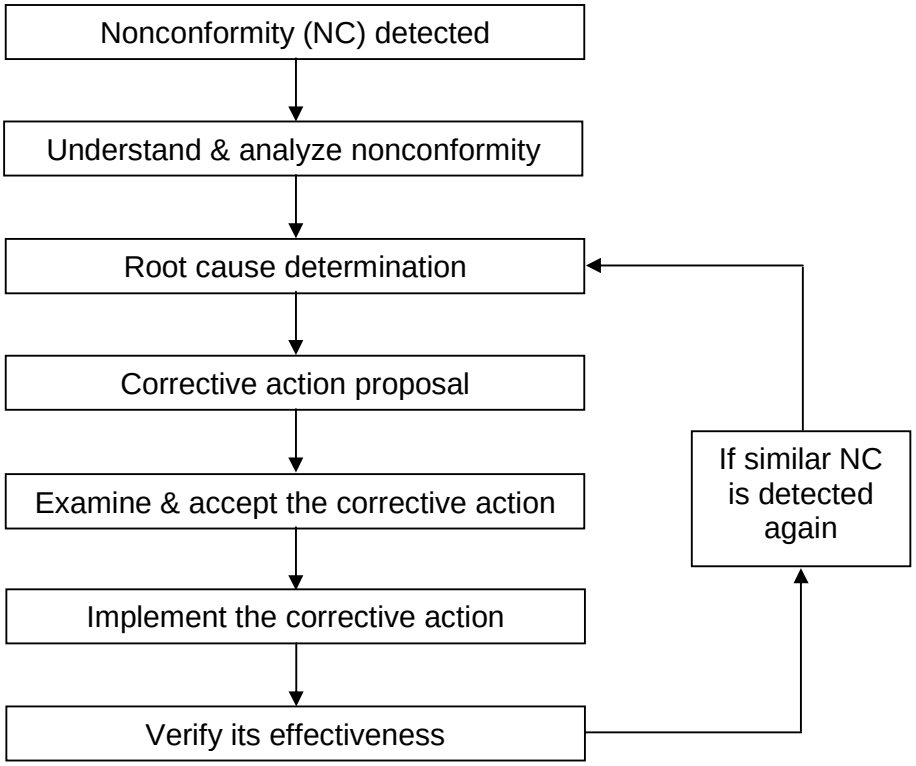
Most of the time, correcting the detected nonconformity becomes priority and this action results only in correction. For example if a report issued by a laboratory has mistake, which is pointed out by the customer, the laboratory promptly corrects the report. The laboratory continues to perform this correction even if 10 customers approach with mistakes in 20 reports. Again, when a lathe machine in the production floor stops because the fuse blew, immediate steps are taken to replace the fuse. If it blows again, perhaps replacement this time would be with fuse wire of thicker gauge. This again is a case where correction was taken.

Corrective action generally has two activities. First is the remedial action, which should be taken to correct the problem. The second activity is the action to control and prevent recurrence of the problem. In majority of cases, an organization confuses Correction as the Corrective Action and does not take the vital second action, i.e. control and prevention of recurrence of the problem. Unfortunately, this confusion is not limited to organizations. Even many auditors and assessors accept correction as the corrective action.

3. WHAT IS CORRECTIVE ACTION

After selecting the problem or the nonconformity for corrective action, first step is to find the root cause of the problem. This is followed by proposing the action for correcting the cause of the problem. The action is then examined for feasibility of its implementation from resource and economics point of view. If considered suitable, implement the action. Thereafter, monitor the effectiveness of the action, i.e. check whether the original problem is recurring. If no problem recurs, then only the corrective action is considered to have been taken. If the problem recurs, re-examine the root cause analysis and propose & implement a different or modified corrective action.

Corrective action may be represented graphically in the following manner:



Corrective action is taken to eliminate the cause of a detected nonconformity. There can be more than one detected nonconformity. Corrective action is taken to prevent recurrence. Correction relates to containment whereas corrective action relates to the root cause of the problem or the nonconformity.

4. SELECTING THE PROBLEM FOR CORRECTIVE ACTION

While efforts should be made to correct every nonconformity or problem detected in the quality & management system, corrective action is always taken selectively. Following are the sequence of selecting the problem for corrective action:

i) Document the detected nonconformity or the problem
ii) Determine the significance of the problem based on :
- risk of not taking corrective action
- problem is significant in terms of impact on resources, schedule, or safety;
- trend indicators suggest the need for corrective action;
- problem is of recurring nature;
- problem is not clearly understood to be insignificant or benign;
- problem is an unexplained anomaly.

iii) If the problem is significant, then decide on taking corrective action

If proper record of detected nonconformities or problems is not maintained, it would be extremely difficult to conclude the significance of the problems. Unfortunately, in most organizations, people are reluctant to record the problems or the nonconformities. This is mainly due to peoples' perception that problems and nonconformities arise out of personal mistakes and recording the same would put them at a disadvantage in the eyes of the management. In order to avail of this important input for corrective action, the onus is on the management to induce & motivate people of the organization to diligently record all problems and nonconformities detected by them.

5. ROOT-CAUSE ANALYSIS

After selecting the problem or the nonconformity for corrective action, the next step is to investigate and find the root cause of the problem. This can be achieved by a team of persons related to the problem by

i) examining the quality records
ii) carrying out investigation through interaction with concerned persons including the head of the concerned sectional laboratory
iii) adopting 5 to 6 level questioning technique using "WHY" or use a fish bone diagram for more detailed cause and effect analysis.

Toyota Motor Company developed the practice of asking "why" five times and answering it each time to uncover the root cause of a problem. Following are few examples of this technique:

Case-1

The daily Quality Control (QC) result was found outside the tolerance limits. The result was, however, within tolerance and thus satisfactory when fresh vial of QC serum was used. Similar situation occurred after 7 days and was solved like before. The problem again recurred after 7 days. The Technician brought this to the notice of the Laboratory Director who adopted the "Why" questioning technique as shown below:

Question 1 Why was the QC result an outlier?
Answer 1 Because the prepared QC serum was not of the correct strength
Question 2 Why did the QC serum not have the correct strength?
Answer 2 Perhaps the QC serum in the vial did not remain stable after being opened

Question 3 Why did the QC serum not remain stable?
Answer 3 Because the QC serum vial was not maintained at the prescribed temperature during storage
Question 4 Why was the vial of QC serum not maintained at the prescribed temperature during storage?
Answer 4 Because it was stored with other chemicals and reagents in the Refrigerator, whose door was frequently opened every day for removal & storage of other items
Question 5 Why was the QC serum vial stored with other chemicals and reagents?
Answer 5 Because the laboratory does not have a second cold chamber

The corrective action was to purchase a small Refrigerator and store the opened vial of QC sera in the same, with instruction that no other item should be kept in this Refrigerator, which was opened only once a day to take out the required amount of serum from the vial. Subsequently, the result of QC serum was monitored and found to be satisfactory till the content of the vial lasted, which was 15 days.

Case-2

The lathe machine on the production shop was frequently stopping due to blowing of the fuse. Every time fuse was replaced and again the machine stopped after some time. Root cause analysis for the problem was performed as under :

Question 1 Why did the lathe machine stop?
Answer 1 Because the fuse blew due to an overload.
Question 2 Why was there an overload?
Answer 2 Because the bearing lubrication of the machine was inadequate.
Question 3 Why was the lubrication inadequate?
Answer 3 Because the lubrication pump fitted to the machine was not functioning properly.
Question 4: Why wasn't the lubricating pump working properly?
Answer 4: Because the pump axle was worn out.
Question 5: Why was the pump axle worn out ?
Answer 5: Because sludge got in along with the lubrication

The corrective action was to attach a strainer to the lubricating pump, after which the machine did not stop due to fuse blowing since there was no overloading.

6. AUDITING & THE CORRECTIVE ACTION

During thorough audit of a quality system, quite a few nonconformities are generally observed. Some of these are minor while some of these could be major nonconformities. While every nonconforming situation should be corrected to the extent possible, no major nonconformity can be closed through correction. Appropriate corrective action must be taken for these. Following examples illustrate this.

Example-1

In a calibration laboratory, one of the internal standards was not calibrated and a major nonconformity report was raised by the auditor. The laboratory proposed either of the following actions:

i) Managed to get the standard calibrated before the closing meeting
ii) Assured the auditor in writing that the standard in question would be calibrated within a week

Example-2

During another audit, a nonconformity was raised because one purchase executive had not been trained to use the ERP software. The organization proposed to immediately train the executive as the corrective action.

Example-3

The laboratory was not conducting internal quality checks as per the requirement of 1 in 25 samples, and the auditor had raised a major nonconformity. The laboratory proposed to start performing quality checks as per this ratio with immediate effect.

All the above actions proposed to close the nonconformities amount to correction. However, a corrective action needs to be taken for closing these nonconformities in addition to taking measures for correcting the situation. First, in all these cases, no root cause analysis is either proposed or performed. Second, no monitoring of the corrective action is proposed or carried out to ensure that these nonconformities are not recurring.

Unfortunately, many auditors, particularly the laboratory assessors accept correction as corrective action. In fact, there are numerous examples where the assessor has raised major nonconformities in the morning and has accepted their closures by the evening or on the next day !

7. CONCLUSION

It is normal practice for certifying or accrediting bodies (third party organizations) to provide a formal written report fully detailing audit findings to the Auditee before leaving the audited organization. Before responding to this report, the Auditee has to investigate the non-conformances, gather data and analyze as appropriate in order to determine the root cause of the problems. It is only then that the Auditee can indicate what corrective action will be undertaken and by when.

It is, thus, not always possible to determine the corrective action at the time of audit. Since the management needs time to undertake the necessary investigations, the Auditor or the Audit team should not force the organization to decide during the closing meeting what corrective actions are to be taken. The Auditor or the Audit team may, however, insist on a time frame within which the corrective action proposals would be submitted to them.

After proposing the corrective action, the audited organization will need to implement the same and undertake their own verification activity to check whether the root cause has been satisfactorily addressed and the symptoms first reported as the nonconformity(s) are no longer evident. This will ensure a meaningful implementation of corrective action!