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CORRECTIVE AND PREVENTIVE ACTIONS IN QUALITY MANAGEMENT SYSTEM

T.N. Sharonina

Tambov State Technical University, Tambov

Represented by Doctor of Technical Sciences,
Doctor of Economics Sciences, Professor B.I. Gerasimov

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Abstract: The paper studies the mechanism of taking corrective and preventive actions enabling to improve the system of quality management.

Corrective actions (**CA**) which are taken to eliminate the causes of some undesirable event should be considered as usual routine work at any enterprise. What is more, corrective actions are inevitable since it is practically impossible to stabilize the conditions of the development, manufacturing, supply and/or assembly of the products rigidly and completely. One important fact cannot be denied – corrective actions actually take place in the organizations from time to time. What's the problem? The answer is obvious. These actions are taken occasionally, in other words they are not system-based. Another problem is that the decisions made on the spot are not properly controlled and as a result, in a few months' time it is difficult to realize what actions have been taken, since new spontaneous decisions which might contradict the previous ones have been made.

In practical work two different notions are often combined and misused. According to ISO 9000 one notion is called "correction", another is "corrective action". In order to understand the ways of improving the system of quality management it is necessary to get to the bottom of the problem.

Let's study the process of introducing corrective actions. Some activity brought a particular result. The result was compared with the given standard at the controlling stage and it was revealed that it didn't meet the requirements (Fig. 1). Our system of quality management aimed at the conformance to the requirements must involve the removal of nonconformance actions. In this particular case we need to make corrections, i.e. to try to correct the result so that it would meet the requirements [1, 2].

Шаронина Т.Н. – ассистент кафедры «Бухгалтерский учет и аудит», e-mail: kir.89@mail.ru, ТамбГТУ, г. Тамбов.

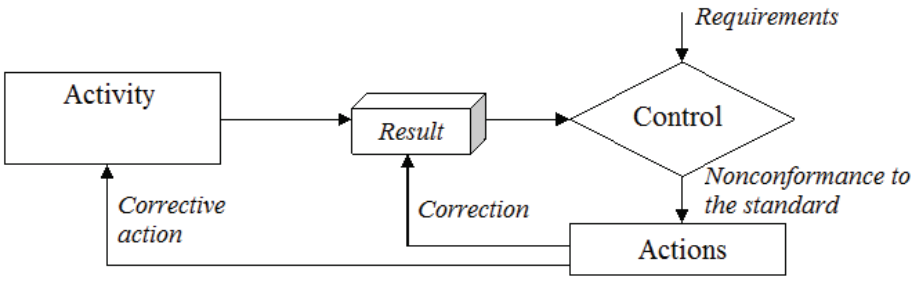

Fig. 1. The process of introducing corrective changes

The main feature of the correction is that it's aimed at the result of the activity; its purpose is to bring the result in conformance with the requirements.

Unfortunately, taking corrective actions affects the specific product and doesn't guarantee that this activity will give the result in conformance with the requirements when it is done the next time. In other words, in order to improve the quality of products we have to analyze the activity and find the cause of nonconformance.

The aim of the corrective action is to eliminate the cause of nonconformance. It means that after corrective action has been taken we mustn't have mismatches.

Corrective action shouldn't be taken if there is more than one nonconformance. It can lead to a high risk of wrong identification of the cause and making incorrect changes in the system. Corrective action must eliminate system causes, i.e. those which occur constantly. But in order to reveal them we need statistics.

We propose a different scheme of taking corrective actions in the quality management system. The proposed scheme should meet the following requirements:

– meet the Clause 8.5.2 of Standard GOST R ISO 9000–2001;

– have minimum additional paperwork to the existing one in the organization;

– if possible use the existing techniques: existing methods of mismatch identification; regular planned meetings; the existing scheme of document management (including documented procedures and quality management).

With regard for the above-mentioned principles it should be noted that the content and the sequence of the corrective actions are practically the same and typical of any enterprise. Basically, all these operations are stated in the standard. But it is necessary to emphasize some of them, including them into the procedure consisting of five units:

– nonconformance registration;

– analysis of the need for corrective actions;

– monitoring of corrective actions according to the registered nonconformance (the standard contains the term "status of corrective and preventive actions (Clause 5.6.2));

– registration of the taken action;

– analysis of the effectiveness of the taken actions.

Let's study the given sequence in detail.

1. Nonconformance registration

Control actions can be applied to registered nonconformance only. It can be stated that if the nonconformance isn't registered, it is out of the management system.

The degree of nonconformance is the degree of the requirement nonconformance and it can be assessed by:

– points;

– relative values (average relative deviation from the norm);

– absolute values (average deviation from the norm expressed in absolute units).

On the basis of the assessment of the potential nonconformance the risk can be estimated.

It isn't enough to say that nonconformances and mismatches must be registered. If they are supposed to be analyzed it is necessary to determine the sources for the analysis, i.e. the documents which registered these data. The number of these documents is quite limited. The examples are the following:

– general journal of work performance (technical inspection and designer supervision records), some special journals;

– in some cases the designer supervision journal;

– correspondence with the ordering party and other interested parties;

– expert reports and supervision bodies instructions;

– input control journals (or other forms of input control, excluding laboratory reports, shipping documents);

– results of comparison of schedules or contract periods with actual performance in the form of charts of manufacturing processes monitoring, etc.;

– internal auditors' records.

It is important to understand that any additional records with reference to the registered mismatches in these documents are not required.

2. Analysis of the need for corrective actions

The fact of nonconformance registration doesn't guarantee that their analysis will be carried out. There are two reasons for this. On the one hand, the analysis should be based on some generalization and selection. In fact, it is difficult to talk about the need for corrective actions when the leader has a whole bunch of letters and only 10 out of them are of some interest from the point of the analysis of the need for corrective actions. On the other hand, it should be defined which member of the staff is in charge of generalization and which member of the managerial staff is to analyze the result of this generalization. There's a widely-held view that everything that the quality service is supposed to do is quite irrational. Another widespread opinion which doesn't stand up to criticism is that corrective action is always the problem of the one who was charged of nonconformance. Quite often these cases are concerned with the fact that in the course of corrective action the responsibility for their implementation was formulated vaguely.

Let's look at three-step scheme of analysis of registered mismatches to identify the need for corrective and preventive actions.

The first step is nonconformance registration. At this stage the manager who is in charge of this nonconformance can either accept it or reject. It is

possible to reject only those mismatches which look like proposals, reminders, and warnings or not justified. There can be plenty of such mismatches which come from instructions of control bodies. If the mismatch is accepted the leader should assess the need for corrective action in the department and the adequacy of their authority. If there isn't enough authority it I necessary to inform the manager who is responsible for the corrective actions at the first step of the analysis. As rule, it is one of the Deputy Directors or the service which is in charge for preparing reports for this Deputy Director. It the nonconformance occurs in Manufacturing Department the person in charge will be Chief Engineer.

At the first step the data are analyzed by the leader who is responsible for the correctness of the procedures and processes where the nonconformance occurred. Supposedly for successful analysis this leader will require to submit generalized data on mismatches. As a result, it will be necessary to define which divisions are in charge for data collection and how often they do it. It is important to make sure that these data reach the Quality service so that at the third step this service could generalize data registered in the entire enterprise about all the mismatches and submit the report to the CEO for the analysis.

The third step which involves data collection and generalization by Quality Service is one of the inputs for quality management system analysis, i.e. the analysis of the status of corrective and preventive actions.

Both the first and the second steps of the analysis do not require any records keeping, it is appropriate putting the data in the form of the note, table or some other document. Methodically the analysis can be arranged after filling in the Table 1 graphs.

3. Monitoring of corrective actions

After the copies of data about the mismatches have been submitted to the Quality Service, they are controlled. In other words, the Quality Service monitors the corrective actions taken on every registered nonconformance. It should be noted, that corrective action (as well as preventive one) must introduce certain changes (improvements) in the quality management system. In fact, it is necessary to eliminate the cause so that the mismatch never occurs again, i.e. to change the "existing rules". These changes can be made in three directions: staff, resources and technologies (or management techniques). Some scientists mention five directions: staff, measurements, technologies, mechanisms and materials, but the number is not critical.

It should be taken into account that one corrective action can eliminate several mismatches due to the Quality Service performance. But at the same time several requirements must be met.

Table 1

Analysis of the Registered Nonconformance

Data source (document which contains the record about the nonconformance)	The name of the manager who accepted the nonconformance	The department which is responsible for data/period of generalization	The name of the manager who is responsible for mismatch analysis
…	…	…	…
…	…	…	…

First of all, the Quality Service should possess the data on the corrective action taken to eliminate the particular mismatch. In order to remember which action is taken the document which contains the data on this mismatch or its copy should have a remark about the corrective action being taken. So as to understand the mechanism let's try to find out how corrective actions vary depending on the cause of the nonconformance. For many organizations the list of causes is quite typical and limited, it is given in the Table 2.

As you can see from the table, it shows both the corrective action and the document proving this action. The reference to this document can prove the fact that the action has actually been taken. The reference can be made in two ways:

– on the document (or its copy) on the nonconformance there should be a mark about the document which proves that the corrective action has been taken (see the above-mentioned table).

– to the document (or its copy) on the nonconformance the Quality Service attaches another document which proves that the corrective action has been taken.

If the nonconformance was registered by the ordering party's letter, then the Quality Service can put a mark on the letter's copy.

Thus, the Quality Service collects database on all the mismatches and what actions have been taken to eliminate them.

Secondly, the Quality Service isn't just a data collector. It is in charge of taking corrective actions and reminding the senior management about the existing mismatches and system failures. Every reminder should be based on facts – the results of processing data mismatches.

Table 2

List of Corrective Actions Depending on the Cause of Nonconformance

The cause of the nonconformance	Possible solution to eliminate the nonconformance	The document approving corrective action have been taken
Staff	Reallocation of duties	Amendment to duty regulations
	Staff member dismissal	Order of dismissal
	Staff recruitment	Job application. Order of staff member recruitment
	Changes in the staff incentives	Instruction (order) in staff management system
	Further training, instruction on prevention accidents or internal rules (quality management system rules)	Instruction journal or application for training/further training, the copy of the document about the training/further training
Resource provision	Buying of new equipment or information materials	Invoices for payment, keeping accounting records about the purchased resources
Technology (management techniques)	Changes in the requirements to work environment, sequence of actions, introduction of new rules, etc.	Amendments to quality management system documents. Issue of instruction on amendments /supplements to the existing internal rules in the organization

Needless to say, no new documents should be issued. The only thing which is required is to submit the copies of the documents on mismatches to the Quality Service, which should either collect documents proving the corrective actions or make marks on the documents that these actions have been taken.

4. Registration of the taken action

In the course of taking corrective actions the biggest challenge is not the development of these actions but making sure that these actions have been taken and their effectiveness have been analyzed afterwards. In fact, talking about the corrective actions which involve making amendments into the existing rules (either spoken or written) it means reforming of the organization even in the slightest way. But any reforms are always painful. Consequently, they must be controlled. The most obvious way of control is internal audit. In order to use this mechanism successfully one needs written instructions, which will reminds the auditors about the need for checking the changes which have been made.

In future, these changes can become habitual and will be executed without any divergence. Then the document containing these new rules can be withdrawn and excluded from both internal and external audit. But before it actually happens they must be controlled.

The requirement to register the actions being taken enables to keep tight control on it. Therefore, the decision about new rules must be registered, i.e. the new rules must be documented (either in a new document or amendments to the existing one). However, quite often organizations misuse the two different notions – “to register the corrective and preventive actions” and “to register of the intention to take the corrective and preventive action”.

When it comes to the corrective and preventive actions which do not involve introducing changes in the rules then the mark on the implementation of the corrective and preventive action can actually give the possibility to analyze the effectiveness of the taken actions. In fact is it worthwhile instructing the employee (or informing them) if it is more effective to make changes in the existing incentive scheme or dismiss this employee.

Thus, the registration of the taken actions obviously involves the fact of introducing or composing a document proving that the action has been taken. To sum it up, registration doesn’t require making additional notes, but involves comparing and changing documents which are issued in the course of eliminating the mismatch and the registration of mismatch itself which was described in detail in the previous part.

5. Analysis of the effectiveness of the taken actions

Apparently, it is possible to find a lot of ways to assess the effectiveness of corrective and preventive actions effectiveness, but the most obvious one is to get internal auditors to check the area of business where the nonconformance has occurred and the corrective and preventive action has been worked out (the rules and technologies have been changed, the additional resources have been provided, staff improvements or combinations have been made or all these activities have been done in combination).

If the nonconformance is revealed in the course of the audit or a set of audits then it is necessary to have the nonconformance registered and go through the procedure of corrective and preventive action again. It nothing goes wrong then the Quality Service takes this nonconformance out of control and thus finishes the procedure of corrective and preventive action.

In practical work there are certain problems in understanding what “a preventive action” is.

What is “potential nonconformance”? How does it different from the mismatches which can be eliminated by the corrective action? [3]

ISO clauses (3.6.4 и 3.6.5) defining PA (preventive action) and CD (corrective action) mention the terms “potential nonconformance” (PA) and “detected nonconformance” (CA). It means that “potential nonconformance” is “not detected nonconformance”, i.e. the one which hasn’t been revealed yet or the one which possesses a risk of nonconformance, but not the nonconformance itself (in this case the risk means the probability).

In case the nonconformance hasn’t been detected it can be eliminated in two ways:

a) the one which is based on the past experience;

b) the other which is based on the outside experience.

Thus, the suggested procedure doesn’t require big costs on record keeping but it involves designing of the monitoring system to look after the problems and mismatches currently occurring in the organization from the point of their system-based solution. In order to achieve this it is necessary to establish analytical service – the Quality Service (or authorize for functions one or several members of staff of some department or departments).

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Механизм проведения корректирующих и предупреждающих воздействий в СМК

Т.Н. Шаронина

ГОУ ВПО «Тамбовский государственный технический университет», г. Тамбов

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Аннотация: Рассмотрен механизм проведения корректирующих и предупреждающих воздействий, позволяющий улучшить систему менеджмента качества.
