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Don't overlook assessing the effectiveness of your CAPA system and your solutions

by José Rodríguez-Pérez and Manuel E. Peña-Rodríguez

JUST THE FACTS

Corrective and preventive action (CAPA) systems are widely used in many industries to assess how a quality management system is performing.

Often, organizations don't thoroughly evaluate the effectiveness of the CAPA plan, as well as the actions being taken to eliminate the problems.

The authors offer advice on evaluating the system and verifying the solutions implemented are effective and working.

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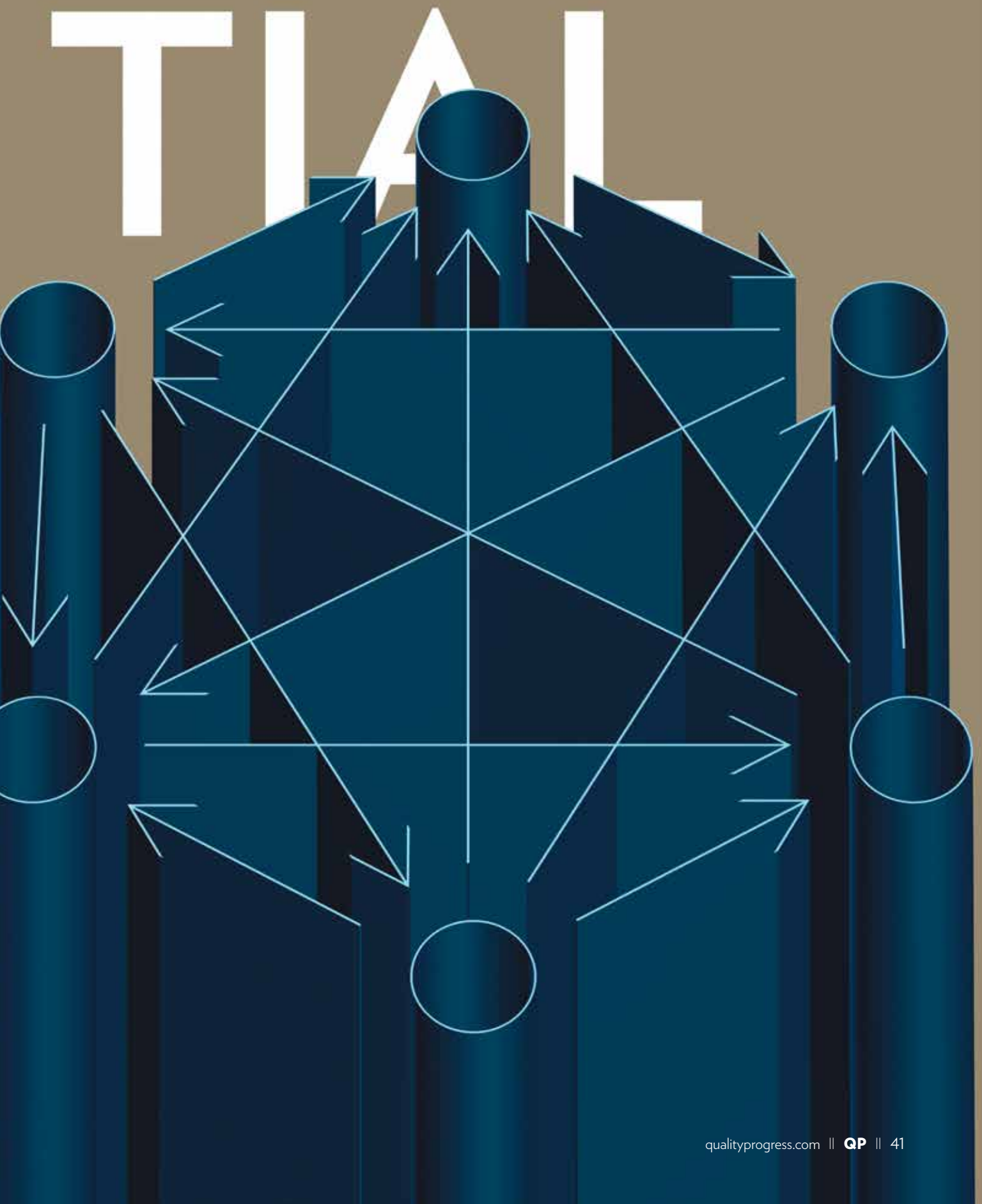

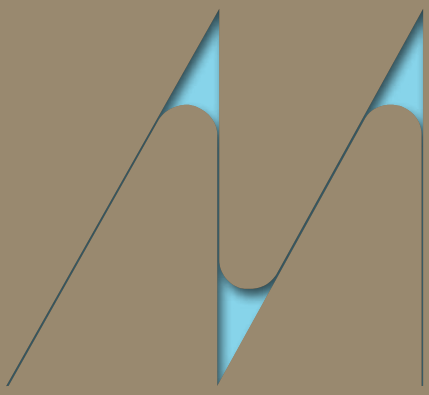

ost organizations devote an important part of their resources to dealing with incidents, investigations, and corrective and preventive action (CAPA) systems. Figure 1 shows the closed-loop CAPA system, which consists of three phases: investigation, the CAPA plan implementation and effectiveness evaluation.

The third phase—effectiveness evaluation—is a critical part of the CAPA system, but unfortunately, this phase often is overlooked. This article addresses that and presents many common pitfalls you may encounter when using CAPAs, as well as some best practices to help you make your next CAPA system most effective.

A robust quality management system (QMS) must monitor its processes continually to identify existing or potential sources of nonconformities. Investigations are performed to find the root causes of any nonconformities. Next, corrective or preventive actions are identified and implemented. Finally, it's time to determine the effectiveness of the corrective or preventive actions. Talking in terms of problems and solutions, we must verify that the solutions actually work. Two main elements here are *how* and *when* the verification is accomplished.

Verifying the solutions worked

One of our favorite things to do at the beginning of a CAPA training session is to ask participants what and how they evaluate the effectiveness of implemented actions. Most participants mention that an action is effective if the problem does not recur. Rarely does someone define it correctly as the lack of recurrence of the same root causes.

After we define what a corrective or preventive action is (the action that addresses the root cause), everyone understands that the effectiveness relates to the causes—not to symptoms or problems. If similar symptoms are observed, don't jump to the conclusion that the action was ineffective.

To be able to conclude this, you must first identify the root causes of this repeated symptom. If you reach the same root cause, you can conclude that the previous action was ineffective. If you discover that, this time, the problem was the result of a different root cause—which is a common situation—the effectiveness of your previous action is not in question.

Within the same line of reasoning, sometimes you investigate a new problem and discover the situation was created by a root cause that you already fixed. In this case, you have evidence that the previous corrective or preventive action was ineffective.

Figure 2 (p. 45) shows the interrelationships between the corrective or preventive actions, and the root cause(s) they are addressing directly. It is always important to specify which root cause(s) each corrective or preventive action is addressing. Otherwise, you will have actions not linked to any root cause(s) not addressed with any action.

There also are some misunderstandings related to verifying the effectiveness of the actions implemented. Some organizations document that the action was implemented—not whether the action worked. If the action is not implemented, it does not have a chance to be effective. The implementation verification is a different concept.

At this point in the CAPA cycle, the QMS requires evidence that the implemented corrective or preventive action was effective, and the intended objective was indeed accomplished.

Root causes are detected through the symptoms they produce. Therefore, to determine whether a corrective action was effective, analyze the process that root cause acted upon. A typical question here is, "How long does it take to verify the effectiveness of the actions?" Some organizations have a fixed period (three months, six months or one year), while others take the correct approach by linking that period to the frequency of the process being fixed.

A rule of thumb we recommend using is the "double-digit" rule. It requires having at least 10 repetitions of the process in which the corrective or preventive action was applied prior to establishing whether the action was effective. If you use a fixed period (for example, one month) and the process is performed weekly, you have only four or five results (in the best case) to determine such effectiveness.

Statistically, there is a large probability that those first four or five repetitions are fine simply by chance—even though the action did not work. By extending the evaluation to at least 10 repetitions, you increase the confidence level. With 10 good results, you can be confident that the action worked.

The documentation of the effectiveness evaluation should be generated along with the rest of the CAPA plan. After documenting the implementation of the action, the only remaining (open) task from the plan is the effectiveness evaluation. The vast majority of CAPA effectiveness plans are totally reactive. We always recommend establishing a verification method that proactively looks for measures of effectiveness.

A typical situation is implementing a corrective action after receiving several complaints on a product. In this scenario, the action is considered effective if no complaints are received

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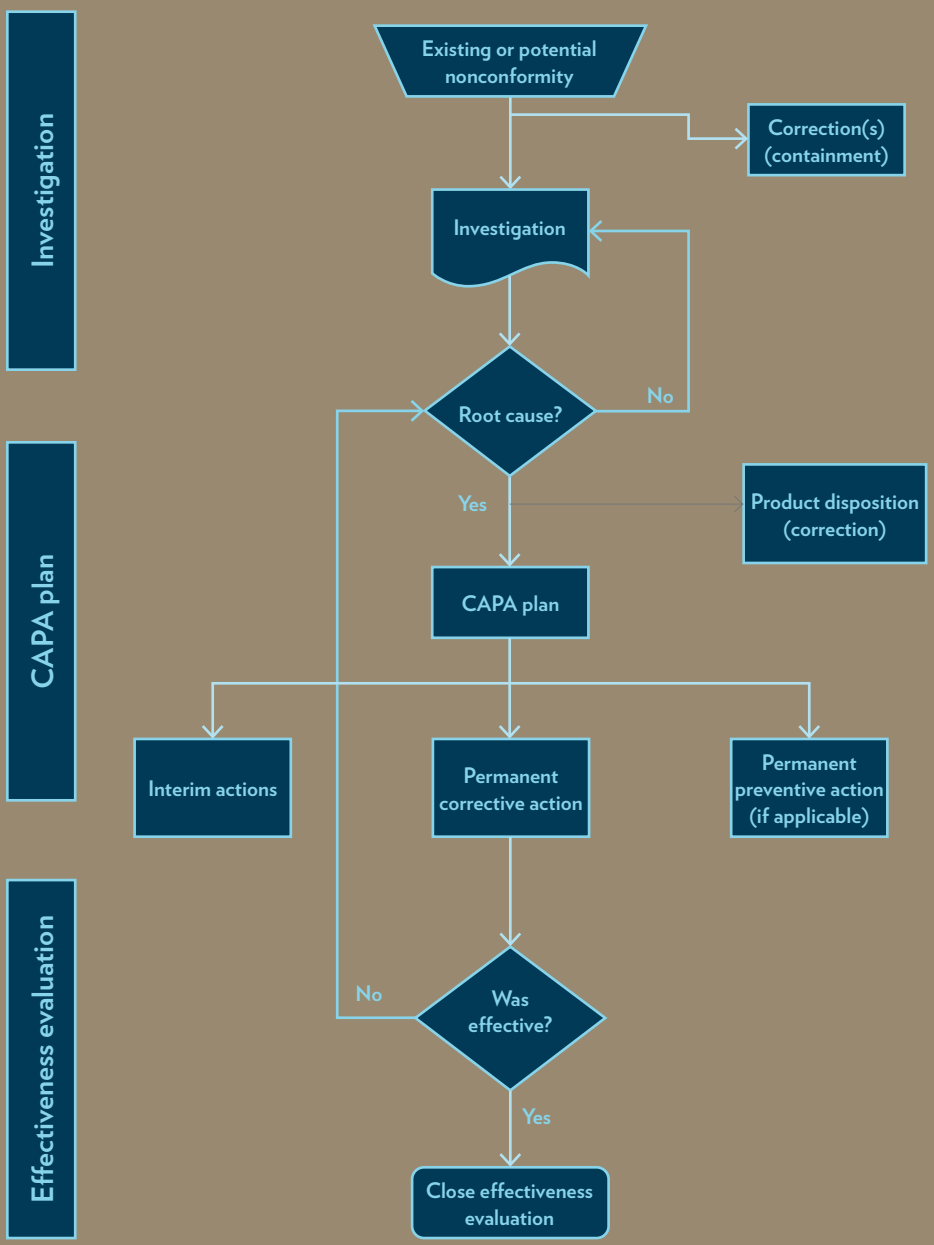
FIGURE 1

Closed-loop CAPA process



CAPA = corrective and preventive action

during the next three months. Lack of complaints does not necessarily mean that the issue was fixed because most complaints are delayed by many weeks or even many months.

A more adequate way to determine the effectiveness of the corrective action is monitoring the next five or 10 batches produced using an appropriate sampling plan. This statistically sound sampling plan can provide an adequate confidence level about the effectiveness of the action.

And yes, it is fine if you also include as a second element of this effectiveness verification some criterion regarding a reduction in customer complaints associated with this root cause.

Training effectiveness

Most corrective or preventive actions require some sort of training or retraining. Measuring training effectiveness, however, is not a task that many organizations perform. Training is a critical component in any organization's strategy, but organizations rarely evaluate the impact of their training programs.

The management of effective training provides the overall structure needed to ensure that training programs have processes in place to support the operations. Organizations that monitor training effectiveness and strive to improve weaknesses are consistently the best performers. It is important to develop methods to measure, evaluate and continuously improve training.

Often, the training function is seen as an expenditure center rather than as one of the most critical activities in any organization, especially in highly regulated environments in industries such as nuclear, aerospace, medical and pharmaceutical. In these industries, training results must be measured. Incorporating selected training metrics into a reporting strategy can help demonstrate the real value of training. Measurements that consider performance improvements can provide a benchmark for training effectiveness.

An important consideration is that most of the corrective or preventive actions are related to some training efforts, and therefore, the effectiveness of these training actions must be evaluated. For most organizations, however, the only record generated from training activities is simply the attendance sheet itself.

When evaluating the possible impact of training during nonconformance investigations, these sheets merely determine whether the personnel involved in the failure signed the corresponding training roster. If so, they conclude that training can be discarded as a root cause of the situation.

READ MORE

For more details on CAPAs, see José Rodríguez-Pérez's *Handbook of Investigation and Effective CAPA Systems*, second edition, Quality Press, 2016. Additional information about the book can be found at asq.org/quality-press/display-item?item=H1504.

However, nothing is said about training effectiveness: Did they like the training? Did they learn something? Are they using what was learned? Has the organization benefited from the training efforts?

Common pitfall: lack of effectiveness evaluation of action taken

A corrective action is considered effective if it can avoid the recurrence of the cause. Therefore, the evaluation of the effectiveness cannot be tied to the presence or absence of the symptom because:

- The same symptom can be produced by different root causes.
- The same root cause can create different symptoms.

There also are misunderstandings related to the verification of effectiveness. Some organizations document that the action was implemented rather than provide evidence that the action worked as intended. From our experience, the two major flaws in the effectiveness verification are:

1. Actions are not clear enough.
2. There's a lack of adequate metrics.

One way to analyze the effectiveness verification statements during investigation and CAPA expert certification is to determine whether those statements have these three elements: actions, a timeframe and metrics.

Examples of inadequate verification of effectiveness include: "The corrective action was implemented," or, "The problem did not appear during the past three months."

An example of an adequate verification of effectiveness is: "During the next two months, a performance evaluation of 15 associates (five from each shift, randomly selected) will be performed to verify compliance with the procedure related to the use of personal protective equipment. Corrective action will be considered effective if all evaluated operators were following the procedure."

Note that this effectiveness verification statement has actions (the performance evaluation), timeframe (two months) and metrics (all operators follow the procedure).

Best practices

When structuring your CAPA system, we strongly suggest clearly defining the evaluation of the effectiveness of the corrective or preventive actions. Also establish statistically sound verification plans, or at least use the double-digits rule of thumb—that is, allow enough time to permit the evaluation of at least 10 repetitions of the process under evaluation.

For a daily process, for instance, one month is a good amount of time to establish effectiveness. If the process is

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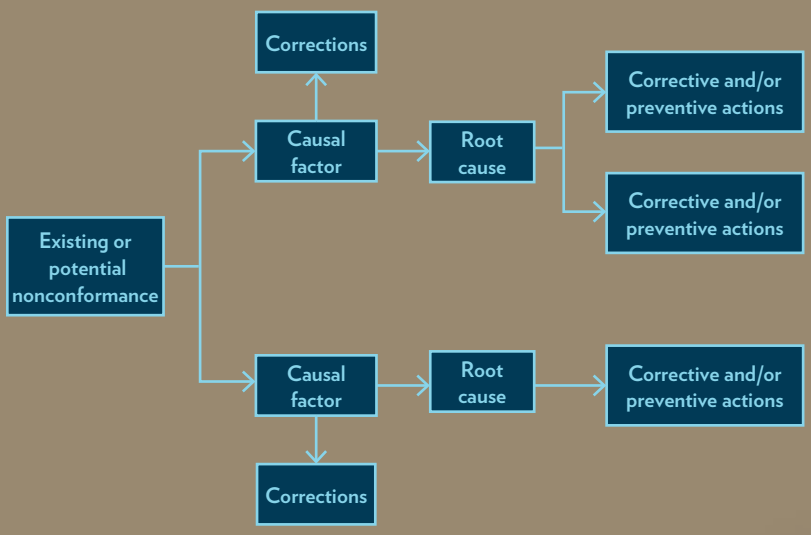
FIGURE 2

Interrelationships between CAPAs and root causes



CAPA = corrective and preventive action

performed about every week, three months should be enough. If the process runs about every month, one year should be a reasonable period to determine whether the corrective action was effective.

Assessing the effectiveness of your CAPA system will ensure you get answers to your questions around nonconformances, and you're able to make the appropriate adjustments to your QMS in a timely manner. **QP**

WATCH OUT

See a two-part webcast on the basics of root cause analysis, including corrective and preventive actions, with James J. Rooney, an ASQ fellow and quality veteran with more than 30 years of experience. To access the recording, visit **https://videos.asq.org/keyword/preventive-action**.

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