



Achieve the Effective Corrective Action That ISO 9001:2008 Requires

Root cause analysis makes your corrective actions stick.

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As more suppliers are required by their regulators and customers to achieve ISO 9001 certification, and because certification symbolizes a point of competitive differentiation in a tight economy, emphasis on meeting the standards is only increasing. Now that continuous improvement has come to be expected, documenting its effectiveness is an increasing challenge because continuous improvement cannot be achieved without the ability to effectively prevent recurrence of quality escapes.

While the ISO standards have long called for a corrective action program (section 8.5.2), the new ISO 9001:2008 standard requires corrective action program *effectiveness* (section 9.5.2, item f). Many organizations struggle to identify and implement a corrective action methodology, and are now straining even more to define, measure, and achieve effectiveness as required by the standard.

Many companies that lead the field in corrective action effectiveness are integrating root cause analysis into their ISO 9001 compliance efforts. Following are best practices and real-life examples gleaned from leading companies.

Beginning the cultural mind set shift

Virtually every corporation experiences ineffective solutions and the recurrence of problems, as well as some accompanying blame, territorialism, defensiveness, and criticism. The first critical step in achieving continuous improvement is a willingness to admit that problems are recurring as a result of ineffective solutions. The second step is to acknowledge the existence of risk and the inadequacy of the corrective action system.

Third, the organization must foster an atmosphere where employees feel respected, and where they trust that any root cause analysis or incident investigation aims to find the facts about all causes—human and conditional—not to place blame. To a certain extent, people must acknowledge that “to err is human,” learn from it, and move on. Discipline is a needed element in the workplace, however, when the organization consistently looks deeper to find conditional causes, people are more trusting that the process is fair, and they see that the solutions are more effective at preventing recurrence.

Many discuss company culture. Culture is no more than the predominate attitudes and behaviors in a workplace. Does your culture focus on blame or on identifying the causes of problems?

Quick fixes versus real solutions

There is a natural human tendency when a problem exists to simply fix the result or effect of the problem, which is then deemed as corrective action. This is really a quick fix, though it may not be seen that way by those who approve and implement it. For example, if a vehicle tire has gone flat because of a nail in the tire, simply filling the tire—without removing the nail and plugging the tire—would clearly not be an effective long-term solution. As obvious as that example seems, in the workplace it’s very tempting to focus on recovering from a problem as quickly as possible and to get back to productive business as usual.

While most people genuinely desire to find “real fixes,” many just don’t know how. Simply put, the mind set needs to shift from fixing the effects of problems to eliminating, changing, or controlling the causes of problems.

Management buy-in

Open support and active endorsement from management is essential to a healthy corrective action program.

So how do you motivate management to change and to openly support change—to be open-minded about changing their view of problems and problem solving?

- Corrective action program champions are most successful in bringing management along when the champions are well-trained in the most proven root cause analysis methodologies. Only then are they truly able to extract its potential, which in turn garners credibility with management .
- Next, they compile practical examples of the results of root cause analysis and cost-benefit analysis, demonstrating the value to management.
- They also carefully compare how root cause analysis results compare to corrective actions that are based on intuition and opinion.

With this background, most managers are won over. They see that the costs associated with running a solid root cause analysis program are far less than the costs of not embracing and supporting one. These include risk, quality breaches, money thrown at ineffective solutions, and customer relations issues.

Managers who stand behind the program are best able to set expectations and motivate the ranks.

Initiating a root cause analysis program

Those who’ve worked with multiple root cause analysis methods might recommend that the following attributes are important to success, so detailed evaluation is important.

Adopt a method that includes careful fact-finding about:

- **People.** How are they performing? What are they doing? Why do they choose to take (or not take) certain actions?
- **Procedures.** Do we have procedures in place? Are they being followed? What training and reference materials are available? Are they adequate?
- **Hardware.** Is it right for the job? What design choices have been made? What specifications are being followed? This includes the human interface to machines and systems, including control and information systems.
- **Nature.** How are natural and external environmental conditions affecting quality? In industrial and manufacturing environments, ambient conditions can be a significant factor.

Look for a method that distinguishes between problems and causes, and that fosters an understanding of cause and effect relationships, as well as the interrelationships between causes. Although you cannot prevent something that's already happened—you can only recover from it—you can drive to the heart of the problem and identify solutions that prevent recurrence.

Beware of methods that only ask “why.” These tend to rely on a lot of guesswork, which is not enough to find the solution. While “why” is important, it tends to focus only on actions, ignoring the conditions that allowed the action to produce an undesirable effect. To be truly effective, you need to go deeper: “What caused it?” Remember that the objective of root cause analysis is not just to create a cause and effect chart—it's to find and implement effective solutions.

Use a method that requires backing up causes with evidence, so you're not just brainstorming problems. Ask for specific examples and references that validate the cost-benefit each method achieves. To earn management buy-in, produce results to demonstrate that you understand each problem and the relationships between the problems. Then provide solutions, showing proof that they prevent recurrence.

There are many available corrective action tools, so choose the ones that are right for you and your company, and fill up your toolbox like a master craftsman.

Choose a provider that offers a holistic approach to help get the program set up correctly, one which avoids wheel-spinning and helps ensure that effective results are achieved—and done efficiently.

Stocking a root cause analysis toolbox

Build your root cause analysis program on a solid foundation:

- Carefully choose as your root cause analysis leaders those who serve as program champions, method experts, and facilitators. You need people with a passion for problem solving and an understanding of why problems occur in the first place. They demonstrate an affinity for the process (which you may observe through the training phase), and they respect the bigger picture. Seeing the bigger picture is important in an effective corrective action program for continuous improvement and ISO 9001 certification. A good rule of thumb is to have one leader for every 10 employees.
- Amass a core of people with basic root cause analysis training so they understand the process enough to be valuable participants for fact gathering in an analysis or investigation.
- Develop comprehensive, documented implementation strategies and infrastructures such as program goals, training strategies, metrics, communication templates, action-tracking methodologies, workflow processes, and clearly defined roles and responsibilities.
- Encourage all key decision makers and players to work directly together to develop a comprehensive program.
- Keep managers in the loop from the beginning, assuring their participation in building the program, which in turn develops active program sponsorship and buy-in.
- Identify critical organizationwide priorities, reflecting the needs of the entire affected entity, so there is no bias toward any particular department or subgroup.
- Identify threshold criteria—predetermined guidelines about when to conduct root cause analyses—that support plantwide goals.

- Assign roles and responsibilities promptly and appropriately based on program goals, the demands of the program, and the availability and expertise of potential program participants.
- Develop a comprehensive change management plan to address training needs and individual needs according to changes in job duties.
- Consider two levels of root cause analysis use. One, a formal approach using preestablished triggers, goals, and documented recommendations with follow up to monitor solution results. Two, an ad hoc use at low managerial levels for minor problems that occur day-to-day and week-to-week.

Utilizing root cause analysis properly

Stick to the four steps of effective root cause analysis, which include:

1. Defining the problem
2. Developing a causal understanding of why the problem occurred (cause and effect chart) which includes supporting known causes with evidence.
3. Identifying solutions
4. Implementing and monitoring the effectiveness of the best solutions

A big-picture, long-term view is needed. When you consider any deviation from one or more business goals, this normally defines the problem that needs to be prevented. Consideration of additional business goals and cost-benefit criteria help prioritize the best solutions—those that do not create other problems. Solutions are implemented to eliminate, change, or control known causes to increase the certainty that the problem cannot occur the same way again.

Root cause is in the eye of the beholder. It is simply the cause or causes that we chose to eliminate, change, or control to prevent recurrence of undesirable events.

Share the knowledge gained from individual and collective root cause analysis throughout the organization so that people can practically apply the findings to their areas of responsibility.

Program evaluation

- Regularly evaluate your root cause analysis program, including roles and responsibilities, as well as thresholds for deciding when the analysis should be conducted.
- Perform a reality check on the volume of the analyses. Are they all being done thoroughly, accurately, and with meaningful results? Are people provided with sufficient time to participate effectively? Are they able to uphold their day-to-day responsibilities?
- Ensure that solutions are being implemented. Are the solutions proving effective? Are the results of the solutions actually changing, controlling, or eliminating causes (effective solutions), or are they only dropping the probability (value-added solutions).

- Create a system to evaluate the effectiveness of solutions. For each root cause analysis, set a date to reevaluate whether the solutions have been effective, or whether the problem has recurred. A good rule of thumb is to look between three months and one year after the close of a root cause analysis. If solutions have been ineffective, decide how you will revisit the problem. Analyze the cause and effect charts to find out what aspects might have been missed.
- Are incident numbers decreasing in all categories? This is a key performance indicator of your analysis and program.
- Are you adjusting your threshold criteria down to analyze less significant events over time?
- Are more people in the organization participating in and supporting the program? Is this spreading to more levels and departments?

Ongoing program development

After the root cause analysis program is up and running, the long term goal is to identify common causes that play roles in quality problems of various types and severity throughout the company, and which could contribute to future problems. With implementation of just a few solutions (that change, control, or eliminate these common causes), the volume of problems decrease at all levels.

Once you have amassed root cause analysis reports over time, dynamic analysis is a powerful way to analyze these previous failures while applying the results to the future. Plug all previous cause and effect charts into a single, larger analysis. This identifies the causes that exist in more than one incident, often referred to as common causes; these also begin to reveal the systemic causes. Common causes that are numerous potentially play a role in future, more serious incidents. A single solution that addresses a common cause can eliminate multiple problems. Precluding common causes reduces your level of risk.

There often is value in performing root cause analysis on seemingly insignificant problems that could have triggered more serious problems. When the causes are eliminated, continuous improvement is attainable.

A root cause analysis program that is well researched, planned, implemented, and maintained is a powerful way to fulfill the new ISO 9001 requirement for corrective action effectiveness.

About The Author

John Stiller, a licensed professional engineer, Six Sigma Black Belt, and long time ASQ member, is director of industrial services for [Apollo Associated Services LLC](#), provider of the world's leading root cause analysis training, consulting, software, and investigations. He spent 26 years at Fortune 500 Ameren Corp., an ISO 9001 environment, where he oversaw major project management and computerized maintenance management systems, as well as business process modeling, improvement, and automation. John also launched and consistently improved Ameren's overall root cause analysis program as a certified Apollo RCA instructor.