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EXPERTANSWE

Nonconformance vs. CAPA

Q: I need advice on using nonconformance versus corrective and preventive action (CAPA) requests. I understand and have tried to communicate the definitions of low risk and high risk to staff. In reporting nonconformances, some evolve into a root cause analysis, which is a positive direction, but it is thought to be a requirement of a CAPA. Nonconformances are logged on a report and reviewed periodically. CAPA requests are more elaborate: logged and reported on a metrics report with continuous review. Can you clarify things for me?

A: My answer may seem lengthy, but I feel defining things is important. First, here is part of a memo I put together for an organization:

ISO terminology and definitions—CAPA: Some people experience confusion over the differences between corrective and preventive action. We know that corrective actions are taken to remove the causes of existing nonconformities. If the nonconformity is detected during production, immediate corrective action is taken to eliminate the problem. In other words, we fix what went wrong. We take preventive action to ensure the same problem does not happen again; however, this is still corrective action because it is based on solving a problem that happened already.

We might use documents or electronic forms to report and record such actions. Here, caution is advised. For example, if a machinist makes a part undersized, immediate corrective action is taken to fix the mistake, and further action is taken so it doesn't recur on subsequent parts. If the original "bad" part was scrap and we record that as a nonconformance in our documentation—with the corrective action noted, we might close that record. We might request a follow-up with preventive action. That would be a mistake.

Note that not every problem or nonconformance requires a corrective action. This is determined on a case-by-case basis, usually by a manager. Each case is different.

For example, a welder accidentally causes weld spatter to fly into a tapped hole. The welder cleans out the weld spatter, retaps the hole and moves on. Generating a nonconformance form should not be necessary in this case because no product was scrapped or made nonconforming.

Suppose an employee sees a potential problem. The employee notices the jaws of a turning center are showing obvious and significant run-out. Potentially, this could result in a nonconforming product. This is a good case for preventive action. A change request could be generated. When the action is taken, it can be verified and recorded in the appropriate format. In most cases, an organization will record few preventive action requests (PAR) over the course of an entire year. However, that same organization will register numerous corrective action requests (CAR). This is the normal rhythm of things, and it's what we strive for.

Here are a few more helpful definitions, taken from ISO 9000:2005:

Clause 3.6.4—Preventive action: Action to eliminate the cause of potential nonconformity or other undesirable potential situation.

- **Note 1:** There can be more than one cause for a potential nonconformity.
- **Note 2:** Preventive action is taken to prevent occurrence, whereas corrective action (clause 3.6.5) is taken to prevent recurrence.

Clause 3.6.5—Corrective action: Action to eliminate the cause of a detected nonconformity or other undesirable situations.

- **Note 1:** There can be more than one cause for a nonconformity.
- **Note 2:** Corrective action is taken to prevent recurrence, whereas preventive action (clause 3.6.4) is taken to prevent occurrence.
- **Note 3:** There is a distinction between correction (3.6.6) and corrective action.

Clause 3.6.6—Correction: Action to eliminate a detected nonconformity.

- **Note 1:** A correction can be made in conjunction with a corrective action (clause 3.6.5).
- **Note 2:** A correction can be, for example, rework.

ADDITIONAL RESOURCES

Coleman, Lance B., "Flow by Design," *Quality Progress*, March 2013, p. 64.

Reid, R. Dan, "Corrective Action Challenge," *Quality Progress*, January 2013, pp. 45-47.

Rodríguez-Pérez, José, *CAPA for the FDA-Regulated Industry*, ASQ Quality Press, 2010.

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When is it good to *gemba*?

Q: I'm planning to start doing gemba *walks at an organization that is at the beginning of the quality voyage. Is this advisable? What do I need to do first to ensure the success of the* gemba *walk?*

A: First, some background to provide context about *gemba* walks. *Gemba* is a Japanese word that translates into "real place"—the place where the action is. When I worked in the construction industry in Japan, we referred to the job site as the gemba. In manufacturing, it's the shop floor. In a hospital, it's the emergency room. In the insurance industry, it's the claims-processing center.

Gemba walks are about getting out of your office chair and observing the actual process, talking with the operators, asking questions and understanding the nature of the work. You're looking for waste, safety hazards and opportunities to improve performance.

This should not be confused with the popular management style known as management by walking around (MBWA) in which managers may occasionally conduct 15-minute "drive-bys," ask about your top three

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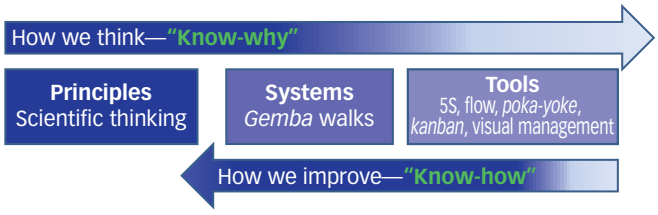
projects, look at your metrics and make small talk. In contrast, *gemba* walks are consistent, cannot be rushed, are substantive and part of structured process-improvement program, such as *kaizen*, lean or Six Sigma.

Leaders and managers are routinely in the workplace, having candid conversations with employees, asking why the work is performed in the manner it is done, looking for opportunities to build relationships with the front line and coach to a structured problem-solving method. Likewise, the *gemba* walk is also an opportunity for the front-line workers to take a break from their day-to-day work activities and look for opportunities to eliminate waste, make the workplace safer, accelerate the velocity of processes and add value.

Gemba walks are central to any continuous process improvement program. As a system, *gemba* walks support the guiding principle of scientific thinking where we insist on direct observation. The tools used in *gemba* walks include 5S, flow, *poka-yoke, kanban* and visual management. However, knowing how to use the tools alone is not enough. Nor is it sufficient to perform *gemba* walks without guiding principles: the know-why (see Figure 1). All too often, people visit other plants only to copy their methods and tools. The problem is they don't know what to copy or why they're copying it.

Continuous process improvement program / FIGURE 1



For these reasons, initially look for evidence that your organization is committed to your quality voyage:

- Are there designated senior leaders who are the champions of change in your organization?
- Has the case for change been clearly articulated?
- Could anyone in your organization, if asked, explain the reason they support the change?
- Could they explain how the outcome will impact the organization and them?
- Have stakeholders been trained with the appropriate tools and techniques?

If you see the signs of evidence, your next step might be to ask yourself some frank questions: Why should you be conducting *gemba* walks? What are you looking to get out of it? Are your leaders and managers committed to investing the time to make the *gemba* walks happen? After you are satisfied with the "why," the rest is fairly straightforward.

Table 1 is a simple framework to help you get started. While I can't guarantee success, I can say your chances for a successful *gemba* walk program can be greatly improved by following these guidelines.

Gemba walk guidelines / TABLE 1

	Pre-*kaizen* walk	*Kaizen* walk	Post-*kaizen* walk
Who	Leaders, managers and supervisors. Designated lead to manage the program.	Leaders, managers, supervisors and frontline. Designated lead.	Supervisors and frontline. Designated lead.
What	Focus on a particular issue. Define objectives and expectations. Scope out the process. Identify resources. The rapid plant assessment (RPA) tool is an effective way to initially evaluate a plant across 11 categories—from safety to teamwork.* The results from the assessment can help you prioritize issues.	**Start of quality voyage:** Focus on a particular issue—such as safety hazards or 5S issues—or issues that are highly visible and can be improved relatively quickly to build momentum. "Rattlesnake hunts" are a great way to kick start a safety *gemba* walk.** **Ongoing quality voyage:** Expand your focus to more challenging issues around quality, flow and bottlenecks.	Create an action plan: Record the issues, assign owners, due dates and status. Follow up with owners as needed. Communicate results via a dashboard.
When	Cadence may vary from daily to monthly, depending on the severity of the issues and what stage you are in your journey. Regardless, maintaining consistency is mission critical. *Gemba* walks must be part of the work routine. It is advisable to take your time on *gemba* walks. Taichi Ohno, a former executive with Toyota, advised, "It should take you hours to walk 100 meters each time you enter the factory. If it takes you no time at all to walk 100 meters that means no one is relying on you." ***		Action plans should be created immediately after *kaizen* walk. Communication of results to the organization should be current.
Where	*Kaizen* walks can begin at the front parking lot and lobby (the first place when a visitor arrives) or at the end of the value stream where the product or service is shipped. With the latter, slowly walk upstream and stop at each major step in the process.		

*R. Eugene Goodson, "Read a Plant—Fast," *Harvard Business Review*, Harvard Business School Publishing Corp., 2002.
**Mark Preston, "Tracking Down Rattlesnakes," *Target Magazine*, Association for Manufacturing Excellence, Vol. 30, No. 3, Fall 2014.
***Taichi Ohno, *Taichi Ohno's Workplace Management*, McGraw-Hill Companies, 2013.

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