THE INFORMED OUTLOOK®

...your source for the latest information on international management system standards

SPECIAL REPRINT

Zero Quality Control: Preventing Defects Before They Occur

Poka-Yoke: Mistake-Proofing as a Preventive Action

By Stewart Anderson

Publisher's Note: This article has been reprinted with permission from THE INFORMED OUTLOOK *Newsletter, March 2002 issue.*

Since the ISO 9000 quality assurance and quality management standards were introduced in 1987, ISO 9001 and the other conformance standards have required organizations to have quality systems containing procedures for corrective and preventive action.

However, even with the improved wording in Subclause 8.5.3, Improvement—Preventive Action, many organizations face two challenges with this requirement:

- Understanding the difference between corrective and preventive action in quality management system (QMS) terms
- Identifying and implementing tools and procedures to help pursue preventive action.

One way to differentiate between them is that a corrective action is a response to a nonconformance in the QMS that needs to be fixed for the QMS to be truly effective while a preventive action is a proactive step to prevent nonconformances from affecting the QMS and the organization in the first place.

While both are important to continual improvement of the effectiveness of a QMS, preventive actions are purely continual improvement activities that constitute a strategy while corrective actions are designed to prevent slippage and maintain effectiveness with an end-goal begin an improved QMS after the actions are taken.

It is important to emphasize that ISO 9001:2000 places greater stress than its predecessors on preventive actions as a means of controlling or eliminating defects from production.

This emphasis is highlighted by the new edition's process approach to quality management, shifting as it does ISO 9001's center of gravity away from assurance and towards continual improvement. An effective ISO 9001:2000 QMS should deliver and sustain measurable and meaningful performance improvement.

ISO 9001:2000 views a QMS as a continual "process" rather than as a series of 20 clauses (ISO 9001:1994). This process approach-oriented standard begins with management's responsibility to provide direction and resources, then moves on to planning and controlling the processes that deliver products and services and concludes with measurement and monitoring with a goal of improvement.

In addition to the preventive action issue raised above, of particular significance is the fact that inputs to the quality management process are defined as "customer requirements", with the output considered to be "customer satisfaction".

Further, the scope of what used to be inspection and testing in ISO 9001:1994 has been dramatically expanded to include Analysis of Data (Clause 8.4). Instead of checking the product (or service) at various stages to "verify that the specified requirements for the product are met" (Subclause 4.10.1, Inspection and Testing—General, in ISO 9001:1994), an organization must now analyze the data resulting from measurements. As a result, there is a new, significant emphasis on being proactive and preventive—the beginning of continual improvement.

Remember, corrective actions address actual problems—they already occurred—while preventive actions address potential problems—they haven't occurred yet. The corrective action process is essentially a problem-solving process, while the preventive action process is a risk-analysis process. In other words, a preventive action is targeted at a potential nonconformity, in that one will most likely occur unless an action to eliminate its cause is taken.

If you truly understand it, ISO 9001:2000 makes it relatively simple to identify potential nonconformities. Objectives must be measurable and requirements must be defined for the measuring and monitoring of processes and products, making the setting of targets for these data gathering activities a natural progression with ISO 9001:2000.

When a measurement trends in the wrong direction relative to the defined target, organizations will want to divert

a problem by taking action. This action would be preventive. The standard asks companies to record and review actions taken, and significant preventive actions should be considered for management review.

On the other hand, if actions are designed not to address a potential issue and an organization merely wants to improve some aspect of its QMS, then the activity is considered continual improvement. In actuality, ISO 9001:2000 does force an organization to assemble a generous tool box with which to perform continual improvement projects: quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

To fully demonstrate continual improvement, companies should be able to present a clear picture of what the situation was before and after improvement actions have been taken.

What Is Poka-Yoke?

What about external tools and procedures to support a preventive action program? One tool any organization implementing preventive action procedures should explore is poka-yoke, a Japanese improvement strategy for mistake-proofing to prevent defects (or nonconformities) from arising during production processes. Poka-yoke is a preventive action that focuses on identifying and eliminating the special causes of variation in production processes, which inevitably lead to product nonconformities or defects.

As I will show you, poka-yoke offers a strategy for preventing defects at the source that is both cost-effective and easy to understand and apply. It is also a valuable tool to add to your organization's continual improvement tool box, if applicable. While at heart a preventive action, poka-yoke is a continual improvement strategy that offers a way to move the QMS towards a higher level of performance.

The poka-yoke concept was created in the mid-1980s by Shigeo Shingo, a Japanese manufacturing engineer. Shingo is well-known for his revolutionary work at Toyota and other Japanese companies, where he developed entire production systems focused on achieving zero defects in production.

Behind poka-yoke is the notion that it is not acceptable to produce even a small amount of nonconforming product. To become a world-class competitor, an organization must adopt not only a philosophy but a practice of producing zero defects. Poka-yoke methods are the simple concepts for achieving this goal and are a key component of the continual improvement strategy in many leading Japanese companies today. Because of its preventive nature, poka-yoke represents what the Japanese refer to as "good kaizen", or superior continual improvement.

How does poka-yoke work? Essentially poka-yoke devices are installed upon process equipment to eliminate or reduce the possibility of error. The specific devices that are employed will depend upon the nature of the process they are used on, but the most common types of poka-yoke devices are inexpensive modifications to process equipment, including such things as locator pins, limit switches and interference pins. Their purpose is to reduce the variability that exists in processing and to ensure consistent, defect-free production.

Poka-yoke devices work because a nonconformity can only be in one of two states—it is about to occur or has already happened. Poka-yoke devices employ three basic methods to prevent product defects:

1. *Shutdown*. Poka-yoke devices monitor critical process conditions and shut down the process when a parameter moves out of the desirable range, indicating that a defective product has either been produced or is about to be produced.
2. *Control*. Poka-yoke devices are installed on process equipment and/or workpieces, making it impossible to produce defects and/or to flow a nonconforming product onto the next process.
3. *Warning*. Poka-yoke devices signal to a worker that a defect has been produced. The worker must intervene to correct the process(es) responsible for causing the defect, since otherwise the process(es) will output further nonconforming product.

Shingo cited an example of poka-yoke in action in *Zero Quality Control: Source Inspection and the Poka-Yoke System* (Productivity Press, 1986). Suppose a worker must assemble a device that has two push-buttons where a spring must be put under each button. Sometimes the worker will forget to put the spring under the button and a defect occurs.

A simple poka-yoke device to eliminate this problem was developed. The worker counts out two springs from a bin and places them in a small dish. After assembly is completed, if a spring remains in the dish, an error has occurred. The worker knows a spring has been omitted and can correct the omission immediately.

While the process of having the worker examine the dish involves minimal cost and interruption, it effectively functions as a form of inspection that is an important addition to prevent defects. The cost of rework at this point is also minimal, although the preferred outcome is still to find the dish empty at the end of assembly, which avoids even the small cost of rework at this stage.

Shingo's example also demonstrates that poka-yoke performs well when the preventive action is aimed at eliminating

operator oversights and omissions. In such cases, poka-yoke devices can be an effective alternative to the usual exhortations for greater worker diligence and application.

Another example would be the spot-welding of nuts on a workpiece. In this case, the workpiece and an inserted nut are set in a jig on a spot-welding machine and are welded together. However, it is possible that a workpiece without a nut in place could be welded, thus yielding a defective piece.

The poka-yoke solution in this case is to install a photoelectric detector and light source on the spot-welding machine. If a workpiece without a nut attached is placed on the jig, then the welding head assumes a lower position on the workpiece and interrupts the light beam, triggering the photoelectric cell. This halts the process and signals to the operator that there is a problem.

Additional examples of poka-yoke devices in action include the following:

- Guide pins of varying sizes that ensure the upper and lower portions of a stamping die are correctly aligned and centered.
- Error-detection alarms that alert workers when a defective part has been produced.
- Limit switches that ensure correct placement of workpieces in machines and processing equipment.
- Counters used to ensure that all processing operations have been completed before transferring a part to the next process.
- Checklists filled out to ensure that all components in an assembly have been installed.

The Relationship Between Poka-Yoke and Inspection

Shingo differentiated between three different types of inspection—judgment, informative and source. Judgment inspections discover defects by sorting the defective pieces out from finished products. Judgment inspections gave rise to the term "inspecting quality into a product". Shingo agreed with the consensus in modern quality management that "inspecting in quality" is not an effective approach to realizing quality and he advocated against its use.

Informative inspection, on the other hand, uses data gained from inspection as feedback to control and improve the process and reduce the occurrence of defects during production. Traditional statistical process control (SPC) is a type of informative inspection. In Shingo's Zero Quality Control (ZQC) system, both successive checks and self-checks are also a type of informative inspection.

Successive checks were Shingo's response to the insight that the speed of improvements is a direct function of the timeliness with which quality feedback is obtained. Typically, work-in-process undergoes many processing steps as it is moved through a manufacturing facility, but inspections are often not conducted until the intermediate stages.

Shingo's concern was that inspections may not occur soon enough after a production process to give the timely information necessary to determine the cause of the quality problem and to prevent its recurrence in the future.

His solution was to have each operation inspect the work of the prior operation, so that quality feedback can be provided back upstream almost immediately.

Implementing successive checks involves having the nearest downstream operation check the work of the operation that feeds it. Under this approach, each operation in the flow performs a quality inspection. Effective poka-yoke devices make such an inspection system possible by reducing the time and cost of inspection to near zero.

Because these inspections entail minimal cost, every item may be inspected. Provided that work-in-process inventories are low, quality feedback used to improve production processes can be obtained very rapidly by the upstream operation that needs to make an improvement.

While successive checks give rapid feedback, carrying out self-checks by having each worker use poka-yoke devices that allow him/her to assess the quality of his/her own work provides even faster feedback. Because operators check every unit produced, they are able to recognize what process conditions have changed when a defect is produced. This insight can then be used to prevent further defects (i.e., root-cause analysis). Because of the immediate feedback capability, self-checks are preferred to successive checks whenever possible.

Shingo believed that, while informative inspections and self-checks each had their place in quality management, the most significant form of inspection was source inspection. Source inspections attempt to eliminate defects by determining that the conditions necessary for defect-free production exist prior to the commencement of actual production.

Under a source-inspection system, poka-yoke devices are employed to ensure that the optimal conditions for error-free production exist and, in fact, prevent the production process from beginning until such a state has been realized. The spot-welding example given above showed how poka-yoke devices can be used to perform source inspections and ensure that the conditions necessary for defect-free production exist.

You may be thinking that poka-yoke really represents corrective actions that involve root-cause analysis. However, what a poka-yoke strategy really does is add preventive actions to an organization that will result in the earlier detection or prevention of product and process nonconformities, permitting corrective actions to be taken instantaneously if they are needed at all.

There is still some overlap between being corrective vs. preventive actions, but poka-yoke represents a continual improvement strategy where the need for corrective actions is reduced or eliminated by improving the QMS's processes.

In summary, poka-yoke is an improvement method whereby Shingo's ZQC can be realized. The aim of ZQC is zero defects in production. As Shingo has written, "The most effective strategies for reaching zero defects are using source inspections to move through management cycles at the level of causes, and using source inspections in combination with 100 percent inspections and poka-yoke devices to speed up

feedback and action."

Thus applied, poka-yoke is an effective technique in the improvement toolbox. When used in combination with source inspection, it permits an organization to launch preventive actions while systematically moving the QMS to a higher level of performance. That is the ultimate goal of preventive action. ###

Stewart Anderson *is President of Kaizen Solutions, Inc., a Toronto-based company specializing in providing systems-based consulting, training and information services to organizations desiring to improve their performance through the deployment of continual improvement strategies and tools. For more information on Kaizen Solutions, visit its web site (www.kaizenimprovement.ca). Mr. Anderson is also a member of* THE OUTLOOK*'s Editorial Advisory Board and may be contacted by phone (905-436-1643) or e-mail (stewart@kaizenimprovement.ca).*