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The question that arises in the discussion is, "Who is responsible for a shift in focus to increase improvement efforts?" Pitfall number one in Barnett's article discusses a lack of leadership engagement. For change to occur, an environment for process improvement must be established; it is necessary for management to emphasize the need and reward the successes. With that stated, it is usually the local inspector or subject matter expert who must change his or her processes. It may be necessary to gather additional data points, but that is rare.

Change comes into play in how the data is used or analyzed. Unless something in the system has changed, looking at the data from the same vantage point would produce the same results. If a concern is identified from the same vantage point, then the problem should have already been addressed—odds are the results would appear to be within acceptable parameters. This standardized approach often overlooks the opportunity to increase productivity.

For instance, many metrology laboratories are separated into measurement disciplines. When looking at raw data it may appear that the laboratory is operating efficiently: Quality rates are within expected rates and throughput times are within established norms. From a macro-level view there would be no need to adjust processes as long as the quality data remains within acceptable limits. When analyzing specific measurement discipline areas and specific technicians, the view may change. For instance, a single area may be providing most of the nonconforming data points while the remaining areas are high performing.

By analyzing the data from different views, a concern that would allow an opportunity for process improvement rises to the top. This becomes important for two reasons. First, by catching the improvement opportunity early it is still small in scale and is probably easier to manage. Second, the improvement opportunity is able to be addressed before it has spread into other measurement areas and could become more difficult to address. While this may appear obvious and simplistic, the mindset can be applied to complicated situations as well. Chasing the checklist may be caused by a change in the inspection criteria or by a slow approach to a status quo. Either way it is necessary to continue to challenge accepted practices and look for opportunities to increase process effectiveness.

This is not to say that checklists themselves reduce capability in continuous process improvement. To the contrary, the most effective organizations I have inspected utilize many checklists. It must be understood that a checklist is a tool, and the tool may be created by the organization using it. Because of this, the checklists can be altered to best fit the needs of the organization and increase the effectiveness of the tool. The user must ensure the proper use of the tool and understand the tool's limitations. The bottom line is, use the checklist—it is a valuable tool—but also focus on proper data analysis and the use of additional tools from your toolbox to seek out improvement opportunities early.

Reference:

 Oli Barnett. "6 Critical Pitfalls That May Hinder Your Continuous Improvement Journey...be honest, do you recognise any?" July 7, 2014. LinkedIn. December 28, 2015. https://www. linkedin.com/pulse/20140717172242-85848069-6-critical-pitfalls-that-may-hinderyour-continuous-improvement-journey-behonest-do-you-recognize-any

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Measuring Quality Control Effectiveness

by Ray Harkins

Aside from meeting specific requirements within quality standards such as ISO 9001 and ISO 13485, well-designed quality system metrics can also serve as meaningful indicators of the strengths and weaknesses of your organization's processes. As a quality manager, I often consider how precisely our quality system objectives and other metrics describe the effectiveness of our quality processes. Certain metrics such as customer-reported DPPM and customer survey results usually serve to indicate your customers' satisfaction related to quality. As metrics such as these are tracked over time, managers get a general sense of improvement or decline. Composite measures such as these, however, do not discriminate between quality assurance (preventive) and quality control activities.

Recently, I was considering the effectiveness of my company's quality system in shielding our customers from our production processes' failings. In other words, we know that our manufacturing processes aren't perfect, and that they do create defects. Therefore, we have several quality control systems in place designed to cull these defects from the material we ship to our customers. These systems include various automated inspections, manual sorting, rework, auditing, etc. And so the question is: How effective is the sum of these quality control efforts?

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Most organizations measure their internal rejects by part number, process, or some other logical grouping. Similarly, organizations also typically measure their customer-reported defects by percent defective or DPPM. By combining these metrics, an organization can determine the effectiveness of their quality control processes.

Consider the data table of internally and externally reported defects and their associated DPPM values by year shown in Figure 1. Columns C, E, and G show the actual number of reported defects internally, externally, and in total, respectively. Columns D, F, and H use the values from column B (PCS Shipped) and the reported defects to calculate Internal, Customer, and Total DPPM, respectively. See the formula for DPPM below:

 $Defective Parts per Million = \frac{Defective Parts}{Total Parts} \times 1,000,000$

In this case, we see year-over-year improvement in both Internal and Customer-Reported Defects and DPPM. This suggests that certain factors such as continual improvement activities and product mix are leading to fewer total defects in the product stream. This is welcomed news for any organization, but the typical product quality metrics stop at this point.

The Quality Control Effectiveness (QCE) metric shown in the far right column of Figure 1 assumes that the total number of defects in the population is the sum of the internally reported and customerreported reported defects. The formula for this metric is then:

$$Quality \ Control \ Effectiveness = \frac{Internal \ Defects}{Total \ Defects} \times 100$$

Using this formula, we can see that in 2014 this organization prevented 89.8 percent of the total defects produced from getting to their customers. We can also see that although the total defects and DPPM trended favorably year over year, the QCE did not. A lower QCE indicates that a lower percentage of the total defects were captured prior to shipment.

QCE is essentially a measure of the effectiveness of your defect detection processes. An upward trending QCE could indicate

improving defect detection systems, while a downward trending QCE could indicate degrading defect detection systems or a product mix that contains defects that are difficult to detect. If I were consulting for a company with these quality metrics, I would suggest that they examine their quality control systems. It may be that their inspection methods are not keeping pace with their customers' increasing quality expectations.

Two notes of caution while applying this metric: First, QCE does not account for the severity of the defects produced. Therefore, an organization's QCE may be trending upward while their customer's satisfaction is trending downward if their processes are allowing fewer but more severe defects to escape. Secondly, QCE may be a biased estimator since customer defect data tends to be under-reported, and supplier defect data tends to be over-reported relative to the true number of defects in the population.

While this example uses the QCE metric to compare one year to the next, a quality professional can also use it to make comparisons of part families, manufacturing facilities, or any other logical grouping. Developing metrics that distinguish between defect prevention and defect detection may unlock your organization's next level of quality improvement.

Reference:

International Organization for Standardization, ISO 9001:2008, Quality management systems – Requirements, 2008.

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A C D E F G R Η Customer-**Total Defects Quality Control** Internal Internal Customer Total DDPM **PCS Shipped** Year Reported Defects DPPM DPPM **Effectiveness (%)** (C+E) Defects 2014 6,106,229 32,640 5,345 3,713 608 36,353 5,953 89.8 2013 6,484,036 39,403 3,996 43,399 90.8 6,077 616 6,693 2012 49,111 6,514,161 44,967 6,903 4,144 636 7,539 91.6

Figure 1