Suppose there is a work cell in a manufacturing plant and a new SOP is introduced into the work cell. There will be a formal review in thirty days (1) to determine if the workers complied with the SOP and (2) to evaluate the quality of the results. There are four possibilities:

Case A: Good compliance and good results (*attended class* and *passed exam*). This is good news because the quality of the results were good and compliance with the standard was good providing evidence that the standard was effective. Work system members should still identify and document any compliance barriers and unusual operating conditions. They should also determine if anyone has ideas for doing the work safer, better, faster, or cheaper. A root cause analysis might not be necessary although you could perform a prospective causal analysis for predicting the *causes of future success*.

Case B: Poor compliance and good results (*missed class* and *passed exam*). This is good news overall because the quality of the results were good, but we don't know if the standard is effective because compliance was poor. Work system members should investigate the causes of poor compliance and determine what was actually done instead of the standard. Whatever the workers did—it worked. Perhaps what was done instead of the standard should be the standard! A root cause analysis could be conducted aimed at determining the causes of non-compliance.

Case C: Good compliance and poor results (*attended class* and *failed exam*). This is bad news because work system members complied with the standard, but the quality of the results were poor. How bad were the results? Where did the standard fail? Should the standard be modified? Were the operating conditions different than what was expected? A root cause analysis could be conducted aimed at determining the causes of poor results.

Case D: Poor compliance and poor results (*missed class* and *failed exam*). This is not good news because the quality of the results were poor and work system members did not comply with the standard. We are not sure if the standard is effective because it wasn't truly tested. How bad were the results? Why was compliance poor? What were the compliance barriers? What was done instead of the standard? Whatever was done instead of the standard, did not work! A root cause analysis could be conducted aimed at determining the causes of non-compliance and the causes of poor results.

4.2 Hypothetical Manufacturing Example

Let's suppose a worker in the Molding Section of a manufacturing plant suggested new settings for the injection molding machines in order to decrease defects. The members of the Molding Section agreed that the *suggested machine settings* should be the new standard and so a new procedure with instructions was developed. Compliance with the new procedure and defects per million opportunities (DPMO) was tracked for twenty-four consecutive shifts. Fictitious data is shown in Figure 6. Compliance with the new injection molding procedure increased over the twenty-four shifts eventually attaining 100%. However, there was no detectable improvement (decrease) in the DPMO over the same time period. The predictive theory failed. It is useful to track compliance and the quality of the results over time so that any patterns, trends, or other special causes can be identified. In this situation, there was "Good Compliance" and "Poor Results" which represents Case C in Figure 5. We should investigate where, how, and why the new procedure failed. Were the operating conditions different

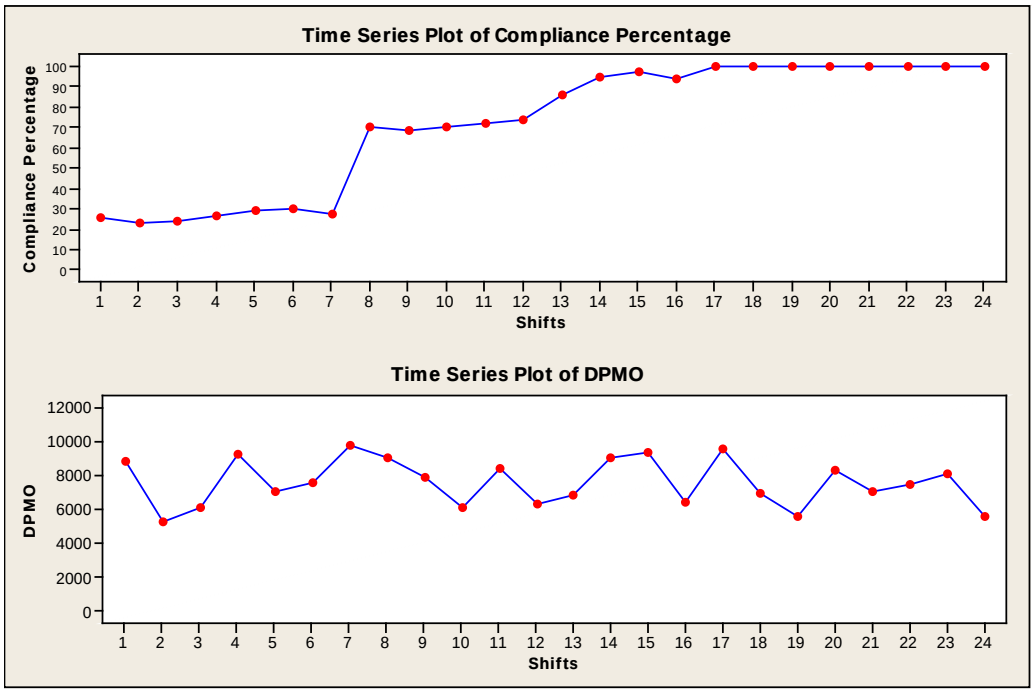

Figure 6. Compliance Percentage and DPMO.

than what we expected? We could conduct a root cause analysis aimed determining the causes of poor results. We could also ask Molding Section members if they have any ideas for how to improve the standard. It is possible for there to be surprises. It might be the case that the new procedure affected other performance categories in a positive way such as improved safety, improved productivity, reduced cost, or improved morale. These would be considered *incidental benefits*.

4.3 Hypothetical Hospital Example

The use of work system standards by clinicians in U.S. hospitals has become common as they attempt to improve the quality and consistency of clinical outcomes and to improve patient safety. Examples include hand washing protocols, standard surgical procedures, standard medication administration practices, and care bundles used for specific situations such as patients presenting with acute myocardial infarction.

Some patients in the Intensive Care Unit (ICU) of hospitals are ventilated. This can be dangerous for patients if they acquire ventilator-associated pneumonia (VAP) which is an airway infection potentially causing death. The Institute for Healthcare Improvement (IHI) in the U.S. has drawn attention to VAP for the past several years as part of the *5 Million Lives Campaign*. There is an *IHI Ventilator Bundle* that is recommended to prevent VAP (IHI (2014)): Elevation of the Head of the Bed; Daily "Sedation Vacations" and Assessment of Readiness to Extubate; Peptic Ulcer Disease Prophylaxis; Deep Venous Thrombosis Prophylaxis; and Daily Oral Care with Chlorhexidine. If the members of an ICU *agreed* on the care bundle, then we would have a *standard*. Numerous studies have been conducted on the efficacy of VAP care bundles (e.g., Pogorzelska *et al.* (2011)).

Suppose that a member of an ICU recommends the use of the *IHI Ventilator Bundle*. The