

Process Improvement Prerequisites

by Kim Niles

At the start of any Six Sigma project, determining sigma levels and defects per million opportunities (DPMO) for the process under consideration seems like top priority. The statistical rigor of the Six Sigma methodology is, after all, one of the reasons for its popularity. In the midst of the preparatory calculations specific to a Six Sigma project, however, it can be easy to forget about more generic prerequisites that apply to any process improvement project, regardless of the methodology.

Before a process can improve, it should first be defined, measured, understood, and held in control. Six Sigma provides many of the different tools and techniques to accomplish these tasks, but there is a gap in Six Sigma literature with regard to these prerequisites. This article provides an overview in an effort to bridge the gap and facilitate more thorough implementation of Six Sigma projects.

Process Definition

Defining a process in the context of an improvement project means to describe it thoroughly while considering the following:

- **Process ownership:** All processes must have an owner. While all processes by default have an owner, facilitators or administrators can be assigned by the owners to manage the process.
- **SIPOC:** Suppliers, inputs, outputs, and customers need to be understood before any process can function.
- **Process map:** Flowcharts, maps, and/or value stream maps are used to describe general steps, flow, constraints, and/or SIPOC pictorially.
- **Criteria:** Standards or some other form of acceptance criteria needs to be developed for every step as well as the final output. Every standard needs an associated tolerance. Process goals and objectives also fall into this area.
- **Verification and validation (V&V):** Verifying that equipment and procedures should work and then validating that they do really work is an important aspect of defining a process. Depending upon the type of process and industry, V&V procedures can get very involved. Medical manufacturing processes often require up to twelve different types of protocol and qualification reports for different V&V's, from the equipment level through the entire process to efficacy of the final product in the customer's environment. A large process therefore could have a huge number of required reports.
- **Process documentation:** Written procedures and work instructions often reduce variation in a process.

Process Measurement

Measuring anything is a waste of time without consciously selected metrics that show how a process actually functions and whether enough progress is being made. Data collected on performance, outputs, defect and opportunity counts, and critical to quality characteristics (CTQs), for instance, should be expressed in relation to desired output or other forms of comparisons such as standards or descriptive criteria. The integrity of measurements also needs to be considered.

Since processes almost always require the combination of many variables, completely eliminating variation is impossible. Therefore, to improve a process we try to eliminate only certain types of variation (special cause variation) and optimize other types (common cause variation). Measuring a process requires consideration of both types of variation with attention to the following:

- **Response variables:** A process response variable is the technical term for what is actually being measured. The term "response variable" relates to the measured mixture of special and common cause variation that is generated by a process at any given moment. Examples include products per hour, worker-hours per handler, and defects per handler.
- **Control variables:** Control variables are all those factors that affect the response variables. Examples include personnel, methods used, management, measuring methods, equipment used, environmental conditions, machine settings, and variation in raw materials.
- **Process metrics:** Process metrics describe the distribution of variation in the response variable in terms of shape, location, and accuracy. They refer to either short-term (capability indices CpK, Cp, Cpm, Pp, PpK, etc.) or long-term (SPC, DPMO, mean, standard deviation, mode, median, kurtosis, etc.) compilation of response variable data.

Process Understanding

Process understanding means knowing the effects of changing any key control variable and/or any reasonable combination of key control variables (interaction effects). This also means knowing what variables do not affect response variables used.

Process understanding can be easy to accomplish when the process is obvious, or it can be difficult when continuous variables such as time, temperature, pressure, viscosity, and speeds and feeds interact. Difficult to understand process variables are usually described in terms of significance with corresponding confidence: for instance, we might know that turning a specific knob by 20 degrees increases jam rates by 12% with 87% confidence.

Components of process understanding include:

- **Main effects (1st order effects):** What is the measured effect of changing only one control variable at a time? Example: new hires increase defects per handler by an average of x with y% confidence.
- **2nd order interaction effects:** What is the measured effect of changing any combination of two control variables at a time? Although not usually the case, 2nd order interaction effects can be more significant than main effects. Example: a smaller increase in defects per handler may occur when new female workers are trained along with new male workers, since together a wider range of questions might be asked.
- **3rd order interaction effects:** What is the measured effect of changing any combination of three control variables at a time? This is rarely important for most processes other than where, for instance, chemicals are mixed or temperatures and pressures are used in combination (i.e., continuous variables).
- **Process understanding measurements:** Accounting for how well a process is understood typically occurs through inference via process metrics (see above). However, other ways of describing how well a process is understood use various forms of statistical methods, such as validation and verification (V&V) reports and combined design of experiments (DOE) results.

Process Control and Stability

A process is technically considered to be under control when it contains no special cause variation. However, in practice it is impossible to meet this definition exactly. Therefore, "process control" is a relative term.

Process control metrics can sometimes be exploited by re-defining what is being measured (rejects, opportunities, etc.), or by allowing variation in those measurements (process mean shifts). With exception to reducing process steps during a Lean-Six Sigma initiative, exploiting metrics defeats why we need process control in the first place. A process under control allows us to predict our costs and benefits accurately; thus, we save money with increased control (up to a point) and we enable opportunities for meeting customer expectations.

Statements of process control are made with given assumptions. How much and what types of variation were included in the measurements? Examples include the following:

- Part variation
- Tooling variation
- Human variation
- Time variation
- Location variation

Process stability is a related term often used for short-term control. Process control is considered to be more long term.

Tools and Techniques

Many of the tools and techniques that address the prerequisites of process definition, measurement, understanding, and control exist within or have compatibility with the Six Sigma methodology. Fulfilling the prerequisites can thus become part of the define and/or measure phase in any Six Sigma project.

Tools and techniques vary from company to company depending upon factors such as type of industry, specific operational needs, and software products available. However, all tools and techniques fall within a spectrum of effort required—from individual task levels to full-time sequestered team-based efforts. Each level of effort has an appropriate use depending upon who is involved and how severe the concern for or expectation of success is. Effort-level examples include purely individual efforts, department to-do lists, ticket-based tracking systems, working groups, task forces, Kaizen Blitzes, and Six Sigma projects.

Techniques include methodologies like the plan-do-check-act (PDCA) cycle, DMAIC, and DMADV; software tools; method-based tools such as the seven quality tools; and personal techniques developed for given situations, such as special check sheets and special test fixtures.

Prerequisites for a Fast Start

Even the best-trained Black Belts can flounder at the beginning of their projects if they don't remember during the definition phase to consider these four basic process improvement principles. Process improvement relies on prerequisites of defining, measuring, understanding, and control.

Six Sigma provides many of the different tools and techniques used to accomplish these tasks, and they vary in accordance with effort level and need. Reviewing these basics at the start of every project will enable a fast start that will gain the respect of the team.

About the Author

Kim Niles recently finished a master's degree in Quality Science from California State University, Dominguez Hills, with emphasis in Six Sigma. He received his bachelor's degree in 1984 in Applied Arts & Sciences from San Diego State University through the Industrial Technology Department. He has a wide range of experience using all types of Designed Experiments and has personally performed more than 140 experiments producing an estimated savings to several San Diego companies in excess of six million dollars (soft savings of ~ \$350MM).

Currently a Quality Engineer with Delta Design, Inc., Niles is an officer in three engineering societies (ASQ703, SAMPE, SDEC). He also serves on the advisory boards for UCSD's Six Sigma Black Belt Certification Program and Palomar College's Quality A.A. degree and certificate program.