

Smithers Quality Assessments, Inc.

**ISO 9001 & ISO/TS 16949:
MANAGEMENT'S SINS
RELATIVE TO SPC**

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ABSTRACT: ISO 9001 - MANAGEMENT'S SINS RELATIVE TO SPC

Certification to ISO 9001 based International Quality Standards requires that management understand, document, implement and demonstrate the effectiveness of specific quality practices. When statistical techniques are used, it is imperative that they be used correctly. Statistical Process Control (SPC) is a statistical tool designed to assist operators in controlling a process. Management must select the appropriate method, provide training and implementation and assure effectiveness. Independent, third-party evaluation of the quality system as part of the ISO 9001 or ISO/TS 16949 certification process will provide objective evidence relative to the success or failure of these efforts. When these evaluations indicate that the SPC program is in a state of nonconformity, it is often found that the root cause lies with management's failure to properly understand, support and manage the SPC process.

ISO/QS-9000: MANAGEMENT'S SINS RELATIVE TO SPC

INTRODUCTION

The ISO 9001 and ISO/TS 16949 Standards are a group of internationally recognized quality system standards that form the basis for a well-managed quality process. Even though these standards have only been around since 1987 (1999 for ISO/TS 16949), they have a long history of development and owe a good bit of their history to government and defense requirements such as Mil-Q-9858 and BS 5750.

Those that understand the true meaning of the requirements readily testify to the fact that the standards form the basis for a well-run, efficient and highly integrated company.

They are seen as an effective way to manage the entire business, not just the quality department. There is constant reference to issues like interrelationships, cross functional data transmittal, teamwork and management review. These standards are, in the writer's opinion, the best system requirements to be developed in modern times.

BASIC REQUIREMENTS OF THE ISO 9001 & ISO/TS 16949 STANDARDS

Regardless of the specifics of each paragraph, there are four requirements that are common to all: Management must: Understand, Document, Implement and Demonstrate the effectiveness of the quality system.

The emphasis is upon management. In other words, the top management of the firm must

not only allow or provide for a quality system, they must be actively involved with it. They do not have to be technical experts, such as statisticians or quality engineers, however, they must understand what the ISO 9001 and/or ISO/TS 16949 requirements are and provide for their effective documentation and implementation. Lip service is insufficient. Consequently, when it comes to statistical applications, top management must be sufficiently knowledgeable to provide for proper training, assure that the selected tools are properly implemented and that the results are utilized to maintain and improve the system.

Following clauses from ISO 9001 and/or ISO/TS 16949 impact the use of SPC:

Clause 8.1 General: plan, monitor, measure, and analyze.

TS2 Clause 8.1.1 Identification of statistical tools: identify appropriate statistical tools during the advanced quality planning process.

TS2 Clause 8.1.2 Knowledge of basic statistical concepts: variation, control (stability), process capability, over-adjustment.

In reality, with what is known and published about the power of applied statistics, it is practically incumbent upon management to apply one or more statistical techniques to the control of the manufacturing process. Consequently, in a modern manufacturing environment, it would be rare to find a process that could not benefit from the power of

statistics. The decision, then, is not so much if to apply statistics, but which statistical tools to apply. This gets to the requirement to "Determine appropriate statistical tools." And, by extension, the selected tool must be applied and implemented correctly.

SPC IN THE UNITED STATES

Sometime in the late sixties, manufacturing managers in the United States fell in love with Statistical Process Control. After all, wasn't it SPC that our foreign competitors used to beat us out of market share by producing products with "more quality"? What followed was millions of hours spent in SPC training classes and millions of control charts generated. But what was the result? In those few cases where management truly understood what SPC was all about, both the benefits and limitations, there were measurable gains. Unfortunately, in many cases, all that resulted was a pile of charts and a growing sense of frustration on the part of the workers who were left to implement this new tool. In these later cases, SPC became nothing more than another means of keeping records, oftentimes just to satisfy those customer quality auditors that kept showing up every other week for system audits.

COMMON MISTAKES OBSERVED IN SPC

When SPC is properly understood and implemented, it is a very powerful tool that assists both workers and management in controlling and improving the process. Unfortunately, many SPC applications are full of problems. Some of the more common problems observed are:

* Control limits are adjusted too often. If the process is under statistical control and is stable, there is little need to adjust the limits. Limits should only be adjusted if: a) process improvement can be verified, or b) the process inputs have changed, resulting in a change in process capability (as measured by CPk). Also, be cautious of computer programs that automatically adjust control limits based on some pre-defined protocol.

* Control limits are incorrectly set. Common errors are: a) forcing limits to be symmetrical about the product nominal value (or some other, arbitrary target value); b) failure to use process data to establish the limits; c) arbitrarily setting the limits to some predetermined values, such as 50% of the product tolerance. (The formulas for establishing control limits do not make use of product specifications!)

* A range chart is not used. Some people have the misconception that all that is needed to control a process is to keep the process average centered. This misses the entire issue of piece-to-piece variation.

* Points plotted beyond a control limit are ignored. The usual excuses include: a) "I checked the next few parts and they were okay." b) "It was only one point! I never get excited over only one point!" Obviously, the whole concept of assignable cause has been lost in these instances. (A quick method to evaluate the significance of these beyond-limit points is to perform a short CPk analysis. If the CPk value has not changed

significantly, the point was a true, statistical "freak". If, however, the CPk value has significantly changed, the point was not a freak and, in fact, the process has changed.)

* Very little attention to out-of-control conditions that occur within the control limits. There is common misconception that the only time a process is out-of-control is when a point plots beyond one of the limits. In reality, of several common out-of-control conditions, only one of them is a point beyond a limit. Missed are the "within-limits" out-of-control patterns, such as unexpected trends, unexpected cycles, shifts, stratification, increased variation and few points near the center line.

* Charts get completed, filed, but never or only rarely analyzed. This gets back to the issue of management understanding and responsibility. If SPC charts are only used to keep records or to satisfy outside auditors, there is a tremendous loss of valuable data and knowledge that can and should be used as part of the quality improvement process.

* Charts are maintained by someone other than the process operator. While there are specific, rare cases where this is the best (and perhaps only) way to implement SPC, such as where laboratory analysis is required, this practice misses the whole point of giving the process operator knowledge, authority, responsibility and ownership of the process. As long as someone else is checking the product characteristic or process parameter, it becomes that person's responsibility to control the process.

* SPC training given without regard to the timing of implementation. This is a sure way to waste your training dollars: train in large groups; implement whenever it is convenient, even if it is weeks or months later. By then, most, if not all, of the new-found knowledge will have been forgotten.

* Applying SPC to the process, but measuring the wrong characteristic or parameter or measuring the right characteristic or parameter but at the wrong place. This practice sends the absolutely wrong message to the workers. It states loud and clear that management does not understand SPC nor the process. Having the operator measure something over which he or she has absolutely no control is senseless and downright frustrating.

* Mixing more than one process on one chart. The most common situation occurs on machines with multiple stations, such as a multiple-head drill press. Even though this may appear to be one machine, each spindle must be thought of as a separate process. The same issue applies to multiple cavity molds.

* Control limits are never reviewed and adjusted. This is almost as bad as adjusting the limits too often. The process will change. These changes must be monitored and their effects evaluated. Monitoring should be performed by someone very knowledgeable in SPC. Based on the analysis, charts may be added or deleted; sample frequency may be

adjusted. CAUTION: All apparent changes to the process should be validated before any changes are made to the control charting process, limits, etc.

* Using SPC charts without control limits. This is little more than record keeping. It is okay if, in fact, you are in the early phases of an SPC application and you are just gathering data. However, if management believes that this is an adequate and acceptable way to use "statistics", they have missed the point completely.

* The process is set up well off target. This is a certain way to assure that the process will "run out-of-control". It also demonstrates a lack of discipline and understanding of what the limitations of an SPC chart are and what is required to properly use and interpret a control chart.

* Limits are based upon product specification. This is a very common error, generally made with good intentions. The idea is to force the target to be the nominal specification value and set the limits at, say, 50% of the product tolerance. Of course, this misses the whole point that SPC is based on controlling the capability of the actual process, not wishful thinking.

* Corrective action not noted & recorded. This is a fatal flaw. All that knowledge of what was done to correct a problem is lost. No one but the person involved in the

corrective action benefits. It is permissible to "code" typical causes and corrective actions, provided some sort of analysis (pareto?) is periodically performed to determine if there are any recurring problems.

WHAT DOES A REGISTRAR LOOK FOR WHEN REVIEWING SPC?

When we review a process for proper SPC implementation, we look for the presence of the common errors described above. We also try to determine some general issues, such as:

- * proper chart development
- * proper chart interpretation
- * corrective action noted, acted upon and verified
- * management use of the data.

When there are few errors, and we feel confident about the proper implementation and understanding on the part of management, then, and only then, can we consider the site to be in conformity with the requirements of the applicable standard.

CONCLUSION

This whole issue can be summarized in three statements:

- * Pick the appropriate statistical tool.
- * Use the tool correctly.
- * Management must make use of the data.

Simple, right? In reality, the answer is "Yes!" It is like anything else in life - be sure you understand what it is you are about to undertake. Monitor the results. Adjust your course of action based on your analysis.

SPC is a very powerful tool if properly applied and utilized. It can lead the way to very effective process and quality improvements. However, used the wrong way, it is a waste of time and money and would certainly prevent your company from achieving certification to the ISO/QS-9000 standards and requirements.

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