STATISTICAL PROCESS CONTROL WITH THE HELP OF INTERNATIONAL STATISTICAL STANDARDS

STATISTIČKA KONTROLA PROCESA UZ POMOĆ MEĐUNARODNIH STATISTIČKIH STANDARDA

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ABSTRACT

Statistical process control (SPC) is a collection of statistical techniques and control algorithms that are used to improve the performance of a process, and to reduce variation of final product parameters. The methods of SPC are used to control variation in a manipulated process input variable or in an in-process product parameter that is correlated with a final product parameter. Since the pioneering work of Walter A. Shewhart in the 1920s many techniques of SPC have been proposed. Some of them have acquired wide recognition and have been incorporated in international standards. Observations of industrial practice show that SPC methods are sometimes used in an inappropriate way. Therefore, the promotion of internationally recognised standards seems to be of great importance.

The aim of this paper is to present some of the SPC methods that are described in the ISO international standards. When there is a need to design more effective procedures, a computer decision support system can be used.

1. INTRODUCTION

Statistical process control (SPC) refers to some statistical methods used extensively to monitor and improve the quality and productivity of manufacturing processes and service operations. SPC primarily involves the implementation of control charts, which are used to detect any change in a process that may affect the quality of the output. Control charts are among the most important and widely used tools in statistics. Their applications have now moved far beyond manufacturing into engineering, environmental science, biology, genetics, epidemiology, medicine, finance, and even law enforcement and athletics.[1] Rao[2] stated: "It is not surprising that a recent book on modern inventions lists statistical quality control as one

[1] Montgomery, D. C., *Introduction to Statistical Quality Control (3rd ed.),* New York, 2000 and Ryan, T. P., *Statistical Methods for Quality Improvement (2nd ed.),* New York, 2000
[2] Rao, C. R., *Statistics and Truth: Putting Chance to Work,* Fairland, MD. International Co-Operative Publishing House, 1989

of the technological inventions of the past century. Indeed, there has rarely been a technological invention like statistical quality control, which is so wide in its application yet so simple in theory, which is so effective in its results yet so easy to adopt and which yields so high a return yet needs so low an investment."

The first control charts were developed by Walter A. Shewhart in the 1920s.[3] These simple Shewhart charts have dominated applications to date. Much research has been done on control charts over the last 50 years, but the diffusion of this research to applications has been very slow.

Observations of industrial practice show that SPC methods are sometimes used in an inappropriate way. Therefore, the promotion of internationally recognised standards seems to be of great importance. The aim of this paper is to present some of the SPC methods that are described in the ISO international standards.

In the next two sections of the paper I present a brief description of SPC methods, and their role in quality improvement. Then I focus on the methods which are described in the ISO international standards.

2. STATISTICAL PROCESS CONTROL (SPC) -- ITS ROLE IN QUALITY IMPROVEMENT

The history of SPC began in the 1920s in America when Walter A. Shewhart of Bell Telephone Laboratories developed a control chart. The first control charts proposed by W. A. Shewhart in the 1920s remains in widespread use today. The Shewhart charts were designed to make it relatively easy for process personnel without statistical training to set up, apply, and interpret the charts using only a pencil and paper for calculations. Together with other statistical techniques control charts they constituted a modern statistical quality control (SQC). SPC methods were used extensively during World War II, but lost their importance in the West during peacetime. In the beginning of the 1950s W.E. Deming visited Japan, and convinced the leaders of industry that statistical methods, when applied in industrial practice, may be used as the main tool for the quality improvement. The Japanese have applied these methods very successfully, and have achieved really outstanding results. In the beginning of the 1980s the West recognised anew the fundamental role of SPC in production processes. The people from industry began to use, and sometimes misuse, the SPC methods. The reason of misusing SPC was simple: the lack of appropriate training in statistics. As teaching of statistics is still not a part of a typical curriculum offered to future engineers the role of standards becomes apparent.

The key factor of the quality improvement is the necessity to measure the process output. As the results of measurements are usually of random nature the use of statistical methods seems to be rather obvious. According to Wetherill and Brown[4] simple SPC methods can be used to:

(1) Have evidence of what a process is doing, and what it is likely to do;

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[3] Shewhart, W. A., *Economic Control of Quality of Manufactured Product,* New York, 1931

[4] Wetherill, G.B. and Brown, D.W., *Statistical Process Control: Theory and Practice,* Chapman and Hall, London, 1991.

(2) Provide an assessment of the quality levels your process is currently capable of meeting;
(3) Tell when to look for trouble and when not to;
(4) Provide clues as to where trouble is likely to occur and
(5) Help towards an understanding of the operation of the system and so help in making improvements to the process or product.

From this list of objectives it may be seen that the potential applicability of SPC methods is enormous, provided that they are used appropriately. It is also the reason for using standards in production practice.

3. **CONTROL CHARTS-BASIC TOOLS OF SPC**

Control charts are the main tools for on-line process control. The idea of a control chart is very simple. The results of measurements are plotted on a chart and compared with certain limiting values. Usually these limiting values are plotted on the control chart in a form of control lines. When the result of a measurement falls beyond the control lines an alarm signal is generated. If the control lines are correctly designed, the alarm signal indicates the high likelihood that the process has deteriorated, and maintenance actions are required.

This simple idea is based on the assumption that there are two sources of process variability. The basic source of variability is natural to any process, and is constituted from so-called common causes. When the common causes are the only source of variability we say that the process is in a state of statistical control, or that the process is under control. To be in state of statistical control does not mean that the process necessarily behaves in accordance to our wishes. The level of variability of the process under control may be higher than required. However, in such a case the process quality improvement can be achieved only by redesigning the process.

In production processes, however, there is a second source of variability. The process variation may be caused by some special causes, called also assignable causes. In contrast to common causes which are present all the time, assignable causes occur randomly causing the process to run out of order. Typically, assignable causes may be identified as failures of equipment, inputting of raw materials of low quality etc. When an assignable cause occurs the process should be investigated, and the cause of the deterioration should be removed. The role of many SPC procedures such as control charts is to indicate a moment when an assignable cause occurs.

On a control chart we can plot the results of single measurements, and the aggregate results of measurements from samples, as well. A typical control chart is presented in Fig. 1.

The control chart is based on the idea that if the process is in a state of statistical control, the outcomes are predictable . Based on previous observations, it is possible for a given set of limits to determine the probability that future observations fall within these limits.In its original form, the control chart is a simple time plot of a sequence of subgroup statistics. The points in the plot are compared to limits, which indicate the bandwidth of the variation due to common causes. These limits are called control limits. The width of these limits is such that, as long as all points are within the control limits, it is reasonable to assume that the underlying process is statistically in control. A point outside the control limits is called an out-of-control signal, as it indicates that more variation is present than can be attributed to the effect of common causes of variation. However, due to the random nature of the observations, there is a small probability that an out-of-control signal is encountered while the process is statistically in control. Such a signal is called a false out-of-control signal.

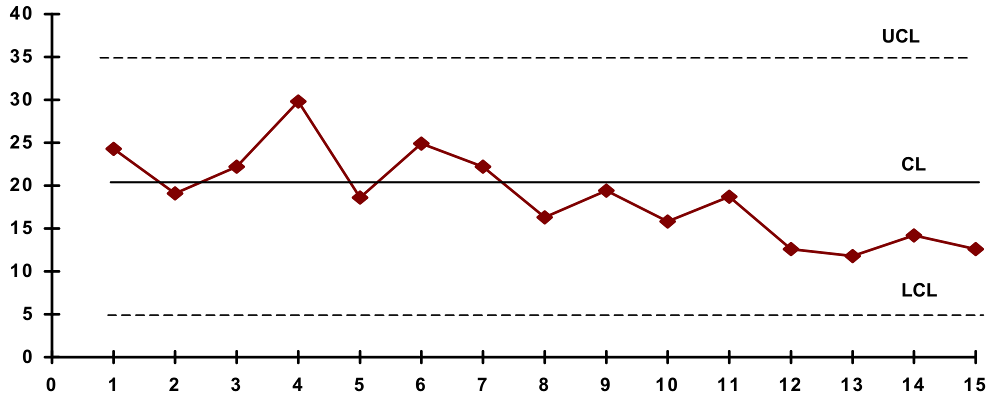

FIGURE 1: TYPICAL CONTROL CHART

From this brief description of a control chart we see the importance of the correct design of a control chart. If the area between the control lines is too narrow we could expect too many false alarms. On the other hand, if the control lines lie too far from a central line, which is usually close to the target value of the process quality characteristic, the occurrence of assignable causes may not be recognised. Thus, the control chart should be designed very carefully. The usage of standards assures that in the majority of practical situations we can design control charts in an appropriate way. However, the best effects from SPC procedures may be achieved when we design these procedures with the help of more sophisticated statistical tools than those offered by the standards.

4. SPC METHODS IN THE ISO INTERNATIONAL STANDARDS

International standards on statistical methods are developed by the ISO Technical Committee ISO TC69. This committee consists of many national members, and more than 20 of them actively participate in the preparation of standards. Standards for statistical methods in SPC are developed by the Technical Subcommittee ISO TC69 SC4.

The ISO standards on SPC may be divided into two groups: general guides, and standards devoted to particular statistical techniques. The general description of statistical standards may be found in the technical report ISO/TR 13425:1995(E): Guide for the selection of statistical methods in standardization and specification.

The general guide for the implementation of SPC methods has not been developed yet. However, the draft of the standard ISO 11462: Statistical Process Control System Standards, Part 1: Guideline for Implementation of Statistical Process Control, is in the final stage of preparation. In this standard the reader will find the guidelines on formulating SPC objectives, defining conditions for SPC, organising a SPC system, etc. Users familiar with the standards of the ISO 9000 series will find this standard very useful.

As mentioned in the third section of this paper, control charts are the most frequently used SPC techniques. The general description of control charts can be found in the standard ISO 7870:1993(E): Control charts - General guide and introduction. In this standard the reader may find the general description of different control charts and their characteristics. Special attention is devoted to the assessment of risks associated with control chart decisions. It is worth while to note here that this particular problem is very often overlooked by practitioners.

4.1 Shewhart control charts in the international standards

To design a control chart it is necessary to calculate the values of control limits. Shewhart, who invented control charts, proposed to set the limits at $+/-3\sigma\theta$, i.e., three standard deviations (standard errors) of the statistical measure being plotted, based on the withinrational subgroup variability. This approach has been proved as extremely efficient by thousands of practitioners. The control charts based on this approach are called Shewhart control charts. Many specialists in SPC have shown by many examples that the use of Shewhart control charts is beneficial in practically every circumstance. The use of Shewhart control limits assures very low probability of false alarms. In general, this probability cannot be precisely assessed without making some additional assumptions. Many practitioners do not bother about their risks, and apply Shewhart control charts without thorough statistical analysis. However, if one wishes to control the risks related to control chart decisions he/she must apply strict formulated rules. These rules can be found in the international standard ISO 8258:1991(E): Shewhart control charts.

Shewhart control charts from ISO 8258 may be used for quality characteristics of variables and attributes type. In the case of variables, the control charts can be used for individual measurements and for measurements of samples taken from the process. When the value of a quality characteristic is assessed from a sample, the sample mean and the sample median are used as the estimators of the mean value. For the estimation of the standard deviation, the sample range R and the sample standard deviations are used.

Shewhart control charts are very effective in the presence of significant shifts of process parameters. However, in the presence of trends, cyclic patterns, etc. the risks associated with false decisions are rather high. In such cases the use of additional decision rules if recommended, based on observations of some characteristic patterns on a chart. These pattern tests are also included in the ISO 8258 international standard.

4.2 Other control charts from the international standards

Theoretical investigations have revealed that the Shewhart control charts are sensitive only to significant process level shifts. To improve this sensitivity additional warning limits have been proposed. The warning limits lie inside the area delimited by the action (control) limits. The area between the warning limit and the action limit is called a warning zone. When either a point falls outside the action limits or the selected number of successive points, K, fall into the warning zone, an out-of-control signal is generated. The control charts with the warning limits may be designed according to the international standard ISO 7873:1993(E): Control charts for arithmetic average with warning limits.

The control charts described in this standard have precisely defined statistical properties. In contrast to the classic Shewhart control charts, the probability of an alarm when the process level shifts by a predetermined value is taken into account, in the design of the control charts proposed in ISO 7873.

The role of a control chart of the Shewhart type is to evaluate whether a process is in a state of statistical control. When a process operates in the state of statistical control it does not necessarily mean that it satisfies product or service specifications. A process may not be in a state of statistical control (for example, when there are cyclic trends in the values of measured quality characteristics), and despite this may satisfy quality requirements. This situation may be observed if this process is highly capable. On the other hand, a process may be very stable, but the fraction of non-conforming items produced may significantly exceed acceptable limits. Thus, Shewhart control charts should not be used alone when we are not sure whether the process satisfies some quality requirements. In such a case they could be accompanied by acceptance control charts described in the international standard ISO 7966:1993(E): Acceptance control charts.

For the acceptance control charts two special process levels are defined: acceptable process level (APL), and rejectable process level (RPL). Any process centred closer to the target value than the APL will have a risk smaller than alpha of not being accepted. If a process is located further away from the target value than the RPL, the risk of its acceptance will be smaller than β. The acceptance control chart is defined by the sample size n, the process levels APL and RPL, and the action (control) limits ACL. The values of the control limits depend upon n, APL, RPL, and the process-inherent variation (which has to be known). The operation of the acceptance control chart is similar to that of the Shewhart control chart. If the plotted point falls above the upper acceptance control limit or below the lower acceptance control limit, the process shall be considered non-acceptable.

In the Shewhart control charts the decision is taken on the basis of the investigation of the last sample (or the last measurement, in the case of plotting single measurements). As already noted, this approach is not sensitive to small shifts in process levels. To detect these small shifts some other statistical techniques have been introduced. They are described in textbooks such as Statistical Process Control: Theory and Practice by Wetherill and Brown. In the case of these techniques appropriately aggregated results of last samples are compared with the control limits. One of these techniques is called a cumulative sum (cusum) technique. On the cusum control chart the cumulative sums of the deviations from the target value are formed, and plotted against the serial number of the observations. The detailed description of this approach can be found in the ISO technical report ISO/TR 7871: Guide to quality control and data analysis using the cusum techniques.

The cusum control charts are more difficult to implement, and should be used by a well-trained staff. However, in some circumstances their application allows the control of the

process in a more effective way. It takes place when even small shifts from the target value could result in negative effects.

4.3 Statistical process control for attributes

The majority of control charts may be used when the quality characteristic is measured by real numbers. However, in many circumstances quality characteristics are of the attributes type (i.e., items are considered either as conforming or non-conforming, or the number of non-conformities per item is counted). In such a case special Shewhart control charts may be found in ISO 8258. It could be noticed, however, that the required sample sizes for these control charts are very often prohibitively large. The reason for this phenomenon is Shewhart's requirement that the probability of a false alarm should be very low. In the processes characterised by a very small fraction of non-conforming items this requirement leads to very large sample sizes. Even if we cannot accept these large sample sizes we can still control the process. In this case we can use the acceptance sampling system described in the international standard ISO 28591:1989(E): Sampling inspection for inspection by attributes. Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.

Sampling plans from ISO 2859-1 are designed for the acceptance sampling of lots consisted of discrete items. For the purpose of process control the entire production between any two successive samples could be regarded as a lot. Then, the results of sampling could be used to evaluate whether the process remains under control. The tables and graphs included in ISO 2859-1 let us choose an appropriate sampling procedure. It must to be noted, however, that it has to be done by people well trained in statistical quality control, as the possibility of the misapplication of these plans seems to be rather substantial.

5 COMPUTER-AIDED DESIGN OF STATISTICAL PROCESS CONTROL PROCEDURES

Statistical process control procedures described in the international standards could be used in the majority of practical situations. In general, the same is true for all procedures of statistical quality control (SQC). There are, however, situations when more advanced methods for their design are required. In such cases even popular SQC textbooks may not be sufficient. The practitioners do not have enough time to look for the solutions that are published in different sources. Therefore, there is a need to develop a computer decision support system which could be helpful in such situations. This need was recognised by a group of specialists in quality control who proposed to build such a system as the EU project. The common project is now realised as the COPERNICUS CP93:12074 project by the group of specialists from the universities in Wuerzburg (Germany), Ulm (Germany), Wroctaw (Poland), and the research institute from Warsaw (Poland).

The aim of the project, that was completed in the middle of 1997, was to develop a user-friendly computer system which could be used for the design of different procedures of statistical quality control. Special stress is put on the identification of the real problem. The accumulated experience shows that many cases of misapplication of SQC procedures are due to the wrong identification of the real problem. If the problem is correctly identified, the appropriate statistical procedures may be applied, particularly those from the international standards.

6 CONCLUSIONS

Statistical process control (SPC) is the main tool for quality improvement. Its basic procedures are described in details in the international ISO standards. The practitioners are encouraged to use these standards, as they could be used in the majority of practical situations. The statistical procedures may by used even more effectively if they are correctly designed. The design process can be supported by the computer system developed under the framework of COPERNICUS CP93:12074 project by a group of specialists in statistical quality control from Germany and Poland.

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