Implementing statistical process control in industry: the role of statistics and statisticians

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Implementing statistical process control in industry: the role of statistics and statisticians
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Abstract

Statistical Process Control (SPC), is an important ingredient of quality management. Although several successful applications of SPC techniques can be found in literature, the implementation of SPC is not as easy as it may seem. Both methodological and organizational problems occur. This paper discusses these problems and how they can be prevented. An historical overview of the development of SPC is used to illustrate that the strengths of SPC is not using statistical techniques but using statistical thinking and empowering people. Based on this overview, the problems in implementing SPC are addressed, especially those that are often overseen by statisticians. A brief discussion of a framework for the implementation of SPC will show how the strengths of SPC can be used and implementation problems can be prevented. Finally, some methodological and organizational guidelines for the implementation of SPC are given.

Keywords

quality control and improvement, statistical process control, spc, implementation framework, statisticians

1. INTRODUCTION

Statistical Process Control, often abbreviated to SPC, plays an important role in quality management. It originates from the introduction of Control Charts by Shewhart in 1924. Although some people still equal SPC with these Control Charts, SPC has evolved from a technique to a philosophy. SPC now includes a large number of techniques and methods directed to quality control and quality improvement.

Although many successful applications of SPC techniques are described in literature, the implementation of SPC is not as easy as it may seem. Some companies do not manage to use SPC successfully and others don’t use SPC at all. There seem to be various causes for this. Some causes are of a methodological nature and therefore are partly addressed by statisticians. However, implementing SPC in an industrial organization takes more than a set of statistical techniques. Therefore also problems of organizational nature occur, but tend to get little attention from statisticians. In this paper both methodological and organizational problems are discussed.

Before these problems are discussed, however, we will give a brief historical overview of the development of SPC techniques in section 2. This allows us to illustrate the scope of SPC and the fact that it is more than a set of statistical techniques. Based on the trends in the development of SPC its strengths and linking concepts are discussed. Besides this the historical overview will provide a background for discussing the implementation problems in section 3.
When implementing SPC one should pay attention to both methodological and organizational problems to omit these problems. However hardly any approaches to implement SPC are described in literature. Those present concentrate on either methodological (Berger and Hart, 1986; Butler and Bryce, 1986; Chaudry and Higbie, 1984), or organizational aspects (Parks, 1983 and 1984; Gaafar and Keats, 1992). Recently a framework for implementation of SPC in industry that pays attention to both types of problems has been developed (Does, Schippers and Trip, 1997). This framework is directed to use the strengths of SPC and to omit pitfalls in implementation. In sections 4, 5 and 6 this framework is briefly discussed.

Section 4 describes phases for implementation and section 5 describes an organizational structure for implementation, both to prevent possible organizational problems. In section 6 a 10-step method is described that presents a coherent set of both statistical and non-statistical techniques to improve and control a process with SPC. This part of the framework is directed to preventing methodological problems. In section 7 the experience in using this method is discussed and the role of statistics and the statistician is addressed.

2. HISTORICAL DEVELOPMENT OF SPC TECHNIQUES

The first application of statistics to achieve quality in production started around 1920. Statistical sampling plans were used for checking batches of products after producing them by taking samples (see figure 1). Examples of such sampling plans are MIL Standards 414 and 105d (e.g. Schilling, 1982). The sampling plan prescribed a sample size and an acceptance number to assess whether the sample didn't contain a higher percentage of products out of specification than acceptable. This percentage is called an Acceptable Quality Level (AQL). The sampling plans were used by inspectors of the Quality Control department in order to check the work of operators.

However, this approach was very inefficient. To achieve low AQL's large samples had to be checked. Furthermore sorting out not accepted batches and scrapping or reworking wrong products was very costly. Although statisticians put a lot of effort in developing smarter sampling plans the drawbacks could only be solved using a different concept.

The change in concept of using statistics was the development of control charts by Shewhart in 1924 (Shewhart, 1931). Based on the variation of a stable process, control limits were calculated from the data. A quality characteristic (such as the mean or range) based on samples taken during the production was compared with these limits to assess whether the process was still stable (see Figure 2). In this way the process would not be adjusted when 'normal' variation caused a deviation of the quality characteristic within a sample. Only if special causes lead to a deviation that was very unlikely to occur (out of control situation), when a process is stable, the process had to be stopped and adjusted.
Although the statistics used were different from sampling plans, the major advantages came from the change of concept. The first change was taking measures and using statistics during production, so that adjustments could be made to prevent a whole batch to be wrong. Secondly the use of control limits instead of tolerances made it possible to control variation and to act when special causes occur. The third was that the control charts should be used by the operators to control 'their own' processes.

Already Shewhart (1931) was well aware that control charts might be sensitive to the assumption of normally distributed process data. He based the limits on a control chart largely on Chebychev's inequality. As a consequence, the probability of an out of control signal using 3σ-limits on a control chart is smaller than 11% irrespective of the underlying distribution, and smaller than 5% for distributions likely to be encountered in practical applications. If the quality characteristic is normally distributed with known mean and standard deviation, the probability of falling outside 3σ-limits equals 0.27%, which is smaller by almost a factor 20. Shewhart argued that the use of "3σ-limits" is an acceptable economic choice. Statisticians adjusted the Shewhart control charts to other distributions and developed other types of charts, such as Cusum charts or EWMA charts, to obtain a better performance (Montgomery, 1996).

When using control charts, it was not always clear how to act when an out of control situation occurs. It was needed to have tools to find root causes for this extra variation to prevent out of control situations in the future. For this purpose simple problem solving tools such as Pareto charts, Ishikawa (Cause and Effect) diagrams and scatter diagrams were added to the SPC "toolkit" (see Figure 3). It turned out that these tools became most effective when used by teams of people involved with the process. In this way, exchange of process knowledge and creative ideas could lead to an effective and accepted solution. Besides a number of non-statistical techniques also statistical tools were adapted from agricultural research. These tools, better known by Design of Experiments (DOE; Box, Hunter, and Hunter, 1978), were used to find causes for problems and to acquire more knowledge of the process.
In trying to find root causes and to really prevent the process to go out of control, the attention is now shifting more and more to controlling process input and process factors in stead of product characteristics (see Figure 4). The goal is to detect (and resolve) problems in the process (or process input) before they can lead to variation in the product. Sometimes control charts are used to monitor a process factor (e.g. furnace temperature), but also non-statistical techniques, related to more traditional technical activities, such as maintenance and automated controls, are used to achieve process control.

![Figure 4: Input and In-process Control: real prevention](image)

A logical next step on the way of prevention was not to start working on the improvement and control of production processes, when production started. Already in trial production, process design or even product design, attention should be paid to prevention of variation and the development of control loops. Statistical analytical techniques such as DOE, non-statistical techniques such as Failure Mode and Effect Analyses (FMEA; Stamatis, 1995), and deployment techniques such as Quality Function Deployment (QFD; Hauser and Clauing, 1988) were adapted to guide the activities from customer needs to a controlled production process and high-quality products.

It may be clear that SPC is more than only using a control chart. SPC now includes also non-statistical techniques; it is not only directed to processes, but also to products, and to organizational processes; besides control also analyses, assurance and design techniques are used. Because SPC is so broad, some people equate SPC with Total Quality Management. In our opinion, however, SPC should be an important part of TQM, but it should not be described in such general terms. In this way it is turned into a concept that is hard to translate to actual production situations.

![Figure 5: Trends in SPC](image)
The strength of the SPC-concept is two-fold and can be derived from the trends in the development of SPC as listed in Figure 5. The first part is Statistical Thinking (based on Hoerl, 1996) which means:

- all work occurs in processes
- variation exists in all processes
- common and special causes should be distinguished
- reduction of variation can be achieved through understanding causes
- less variation is the key to improved quality, productivity, profitability
- the core of SPC is not using statistical techniques but using statistical thinking

The second part is an organizational concept that might be called empowerment. It is about the way people are stimulated to control their own processes and to communicate their knowledge. The most important aspects are:

- using statistical thinking is not only for quality-specialists but for everybody, especially those directly involved with processes
- statistical thinking should be understood and supported by the whole organization
- giving control to people that own the process (e.g. operators)
- using peoples knowledge stimulate communication

In this way SPC is applicable in most situations, including design and other supporting organization processes. This paper is mainly focused on tools used in production processes, but after implementing the concept in production it should be translated and expanded to other parts of the organization.

3. PROBLEMS IN IMPLEMENTING SPC

In literature several reasons for failing implementations can be found ranging from methodological to organizational. Although there is no rigid distinction between methodological and organizational problems, we will start with the methodological problems that are more familiar for statisticians, and end with the organizational problems that may be overseen by statisticians.

In trying to improve the success of applying SPC, statisticians tend to concentrate on developing smarter tools. Researchers in the field of quality technology report on the problems with the suitability of statistical techniques for certain situations, e.g. too little data, and wrong type of distribution. Often an other application or the development of a smarter tool is presented. Although this solves problems with the application of a single technique, many problems still arise when implementing a SPC system in an organization. Some problems are:

- Statisticians often do not realize that the strength of SPC is not only the use of statistical techniques, but the use of statistical thinking and a way of motivating people. Problems arise when SPC is implemented by just applying a set of statistical techniques.
- When using SPC as a concept, it shows that also non-statistical techniques play an important role to use statistical techniques effectively. For instance, a control chart, won't become effective as a control tool until an Out of Control Action Plan is made to make clear what actions should be taken when an out of control situation occurs (Sandorf and Basset, 1993). Often non-statistical techniques receive little attention and are not applied in a coherent way.
- Experts in statistics like to use sophisticated statistical tools and therefore tend to skip the simple statistical techniques. Most of the SPC techniques are quite simple, and are therefore not very challenging from a statistical point of view. Therefore development of complex new tools receives most attention.
Another problem is the wrong use of ‘standard’ techniques. Especially when training people, often standard techniques and standard ways of applications are learned. In many cases, however, it is not possible to use a technique in a standard way. (Roes and Does, 1995). Therefore it is important not to focus on the technical methodological aspects, but to understand its function, goal, and relation with statistical thinking. Different situations may ask for different activities to execute these functions (Schippers, 1997). Training on the job is most effective to learn this. Also the use of a statistical software package can result in the wrong use of standard techniques. The use of a such software may cause people to use techniques without enough understanding of the SPC concept to interpret the results, without the use of technical knowledge, and without doing the necessary work before and afterwards. Besides this most statistical packages only offer standard tools, and don’t allow these techniques to be tailored to specific situations.

Besides these more or less methodological problems, researchers in the field of quality management often report on organizational and social factors. Lack of management and operator commitment, lack of company vision, lack of understanding and lack of training of SPC-techniques, poor project control and fading attention after the first introduction of SPC, are found to be causing unsuccessful implementations or even roadblocks for implementation of SPC (Lockeyer et al, 1984; Dale and Shaw, 1991; Gaafar and Keats, 1992; Mann, 1995).

Based on our experience in SPC implementation projects, we can add the following organizational problems in implementing SPC:

- It takes several years to implement SPC company wide; time and money have to be invested before SPC is fully effective through the whole organization. To prevent that the project collapses after the first introduction, project management and an organization framework are essential
- Constant attention and support of top management is necessary. To achieve this, management should be trained in statistical thinking training during the introduction.
- SPC demands delegation of tasks, responsibilities and authority to the lowest possible level. SPC should not be limited to the quality-department and SPC specialists. Control should be given to operators. This improves the quality awareness and gives people control over their own activities.
- Implementation of SPC has to be guided by an expert with thorough knowledge of the possibilities and problems with statistics (the so-called SPC-consultant)
- The whole organization has to be familiar with tackling problems through the use of data using statistical thinking instead of fire-fighting through a product-oriented approach.
- Teamwork and communication are essential.

A framework for the implementation of SPC has been developed to prevent these problems in production. In the next sections this framework will be briefly discussed. Although the concept of SPC can be used for all processes (e.g. in designing processes and products), it should start in the production department. Therefore the framework is primarily directed towards production processes. In addition we will describe how company wide implementation of SPC sets the stage for Total Quality Management. For a more detailed description of the framework, we refer to Does, Schippers and Trip (1997).

The practical experience of the authors was acquired through active involvement in various projects where the presented approach was used to implement SPC. The companies involved were in mass production (Sara Lee/DE (coffee and tea), Philips Semiconductors (diodes), and Philips Components (Ceramic Multilayer Actuators)), small batch production (Signaal (printed circuit boards), Fokker Aviation (cable harnesses)), and also in low volume production of complex products (ASM Lithography (wafersteppers), and Fokker Aircraft (aircraft)).
4. PHASES IN THE SPC IMPLEMENTATION

Some organizational problems arise when the implementation is concentrated on the methodological aspects of SPC. They can be avoided by carefully planning the implementation phases as described in this section, and by forming an organizational structure as described in the next section. Only after these boundary conditions are fulfilled, it makes sense to start the methodological part using the ten-step method as described in section 6.

Before the actual implementation starts, however, top management should be convinced that SPC contributes to the company’s bottom line. Besides this the pressure of an industrial customer demanding SPC as a prerequisite before any deliverances can take place, can be very stimulating. Philips started introducing SPC because Ford demanded them, and Signaal and Fokker felt strong pressure from Lockheed.

The implementation is divided into the following four phases (as shown in Figure 6):

![Figure 6 Phases of SPC implementation](image)

Phase 1: Awareness (few weeks)
The first step in the awareness phase, that can be seen as the formal start of the implementation of SPC, is an awareness meeting for the staff of the company. The goal is to let the staff become familiar with the Statistical thinking fundamentals of SPC and its implementation. The awareness meeting addresses the strengths of SPC and possible benefits for the organization such as:
- Financial benefits through less scrap and rework, shorter throughput times, and better product quality.
- Better communication concerning producability, specifications and delivery performance.
- The organization will be statistical-oriented: decisions are made based on data instead of assumptions
- Operators become more responsible and involved in the performance of production processes.

In order for the awareness meeting to be a success, a good preparation is necessary and the assistance of an external SPC-consultant can be very useful.

After the awareness meeting a steering committee is formed and top management gives them the assignment to make a plan for the implementation. This should include processes to be dealt with in the pilot projects. The processes used in the pilot phase should be known as problematic (but not too extensive and complex) so that real results can be achieved.

Phase 2: Pilot projects (6 months)
From the start of this phase a project management approach should be used, guided by a steering committee as described in section 5. The steering committee installs a few teams that will work on
the processes selected in the previous phase. The teams, called ‘Process Action Teams’ or PATs, are described in section 5. Each team receives the assignment to bring the process under control using the ten-step method described in section 6.

When the ten steps are executed and improvements are implemented, the process is called an operational SPC point. Depending on the complexity and size of the process, the throughput-time varies from three months to more than a year. This is based on weekly meetings of two hours, if necessary with additional hours in the period when the process is thoroughly analyzed.

To enlarge the commitment and to improve the knowledge of SPC, it can be useful to give an SPC training for members of the steering committee, process engineers, quality engineers and development engineers. The members of the PAT receive a training-on-the-job when using the ten-step method.

After approximately half a year feedback about the results of the pilot projects will be given to the steering committee and top management and a go/no go decision will be made. At this moment the organization may not yet expect enormous return on investment, because firstly the organization needs to learn, and secondly long-term effects cannot yet be seen. However, the organization should be confident that SPC can control processes and improve profits.

Phase 3: Integral implementation in production (1.5 to 2.5 years)

In this phase more Process Action Teams will be installed by the steering committee. The organization structure described in the next section has to become effective. Beginning with the weakest, other processes will be selected and PATs will be assigned to use the ten-step method to bring them under control. All important process steps have to be controlled in this way.

From the beginning of this phase it is necessary to give one person within the company the task of SPC-coordinator. Especially when external SPC-consultants were hired to assist in the implementation, the knowledge and pulling force of these experts gradually have to be taken over by this SPC-coordinator. The SPC-coordinator should become familiar with all the ins and outs of SPC and become the driving force of SPC. In this phase the SPC-coordinator (if necessary assisted by an SPC-consultant) should give SPC-training to all people involved.

Phase 4: Setting the stage for Total Quality Management

After a process is under control the PATs are dismissed and transformed into Process Improvement Teams. They should be part of the regular organization and their task is to assure the control of the process, tackling problems and searching for opportunities for continuous improvement. The tasks of the steering committee can also be transferred to the regular organization.

In this phase the SPC-approach should also be broadened to other parts of the organization. Already in phase 3 the activities in production can have their effect on development, purchasing, customers, maintenance and other supporting activities. In phase 4, however, the SPC-approach should be actively extended to these departments. Other steering committees should be installed to guide the implementation.

The main purpose of SPC is to describe and to know the process; to search for and to improve weak points; to define effective measurements and control loops; and to assess the performance as a basis for continuous improvement. This concept can also be expanded to process and product design, and other non-production departments. When it is implemented in all parts of the organization, and customers and suppliers are involved as well, this leads to Total Quality Management. However, this will take at least five more years: the implementation in a department will take approximately
one and a half year because of a limited capacity to introduce changes, and because not all departments will start at the same time.

5. ORGANIZATIONAL STRUCTURE FOR SPC IMPLEMENTATION

The organization structure that is used to implement SPC consists of Process Action Teams, a Steering Committee and Top Management. The structure depicted in Figure 7 stresses the fact that both top management and steering committee should mainly play a supporting role for the PATs.

![Organizational structure for SPC implementation](image-url)

**Top Management**
Top management has given commitment and has delegated the management of the implementation to the steering committee. Progress is monitored based on reports from the steering committee.

**Steering Committee**
Although the PATs are the core of the SPC implementation, the steering committee plays an important role in initiating and controlling the implementation process. Although in the first three phases the projects will be concentrated on production, involvement and commitment of other disciplines is necessary because the SPC-projects will have consequences for related departments.

To ensure management commitment in production and also related departments, the manager Operations should be chairman of the steering committee and managers of Purchasing, Development, Quality and Maintenance should also be members of the steering committee. The SPC-consultant and SPC-coordinator should also be part of the steering committee. Below the main tasks of the steering committee are listed.

- **initiation and promotion SPC**, e.g. formulate goals and form teams, stimulate SPC-awareness through personal involvement, stimulate teambuilding and recognition, reward results
- **providing method and means**, e.g. time and budget for training and external support
- **controlling**, i.e. monitor progress of PATs, set priority for quality activities, and assess results and certify teams when ready.
- **reporting to top management and advise on quality strategy**, e.g. financial benefits obtained.

**Process Actions Teams**
It is important to realize that SPC cannot be implemented by a few engineers or staff members. SPC should be implemented by teams which include people from all departments involved, but especially operators. Their knowledge and commitment are crucial to make SPC successful. Therefore the approach is based on teams called Process Action Teams or PATs. They should consist of representatives of all directly involved disciplines.
A typical PAT consists of: 2-5 operators (depending on the number of shifts) and their supervisor, a process engineer, maintenance engineer, internal customer, and an SPC-expert. If necessary a development engineer, quality engineer and someone from the purchasing department should be part of the team, but ad hoc support may be sufficient. The PAT is chaired by the person who has the technical responsibility for the process, generally a process engineer. The secretary should be someone with experience in writing reports, for example a development engineer. His task is to make reports on the results and planned activities.

The team members receive a short three-hour introduction to SPC from the SPC-expert. The training is comparable with the introduction for top management during the awareness day, but should be adapted to their level. The rest of the training will be on-the-job, by working through the ten-step method, and by the guidance of the SPC-expert. Because not all operators can be part of a PAT (for practical reasons) it is important that the team members communicate the activities, problems and results of the project with there colleague operators.

The main goal of the PATs is to bring the process under control using the ten-step method and consequently to adapt an organization that supports SPC.


The primary goal is to bring the process under control using the ten-step method summarized in this section. The method has been developed and applied for implementing SPC in the earlier mentioned companies (cf. section 3). It is laid down in a workbook that includes a brief instruction for each step and standard forms for the results. The advantage of using such a workbook is the possibility for training on-the-job, standardization of terminology and the possibility to structure and monitor the implementation. The activities and a typical time frame are depicted in Figure 8.

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Figure 8  Steps and typical time path of SPC methodology
The 10 steps can be grouped around the main purposes of SPC:

- **Steps 1, 2 and 3: to describe the process and search for weak points.**
  In these steps mainly non-statistical tools are used. The knowledge within the team is used to analyze the process. The role of the statistician is to guide the team and train in statistical thinking.

- **Steps 4 and 5: to search for improvements for weak points and to implement them.**
  In these steps first existing knowledge is used to find improvements. If problems can not be solved, additional measurements should be taken and analyzed. Besides simple non-statistical problem solving tools, design of experiments can be used, which may require statistical support.

- **Steps 6, 7 and 8: to define effective measurements and control loops to control the process.**
  In these steps the actual control loops based on control charts are developed. In analyzing the suitability of measurements (R&R-study) and in setting up the control charts support of a statistician can be necessary to tailor the statistics. Finally OCAPs are used to document relevant knowledge on the process and to close the control loop.

- **Steps 9 and 10: to assess the performance and arrange for continuous improvement.**
  In these steps, the performance of the process is assessed and if necessary improved. Support of the statistician can be necessary for tailoring and interpreting Process Capability Studies. Finally the attention should be given that using SPC becomes part of daily work.

The main purpose of this article is not to comprehensively describe all steps, but to give an overview. For each step first a brief description of the activities is given. A statement of the methodological goal, the organizational goal, can be found in Does, Schippers and Trip (1997).

**Step 1: Process description**
In this step the process is described (e.g. with flowcharts) and the boundaries of the process under study are determined. If possible, the process should be divided in process steps that include only one distinct transformation. It is important to describe the actual situation.

**Step 2: Cause and Effect analyses**
For the important process steps described in step 1 the main problems (causes) and their effects are listed. Using Ishikawa diagrams can be helpful (Whadsworth et al, 1986). The problems should be process related, i.e. disfunctioning elements of the process as perceived by operators. Effects should be product-related problems or disruptions of the process leading to downtime. The importance of causes and effects should not be discussed to avoid limited creativity. The importance is determined in step 3: risk analysis.

**Step 3: Risk Analysis**
In this step for each cause and effect relation the relative importance is calculated using a technique similar to Failure Mode and Effect Analyses (FMEA) (e.g. Stamatis, 1995). The risk priority of each combination is calculated by multiplying scores for:
- The frequency of occurrence of the cause.
- The severity of the effect of the cause.
- How well the cause can be detected and resolved when an effect occurs.
Scores rate from 1 for low frequency to 10 for high frequency and so on. Relations with high risk numbers should be analyzed for possible improvements in step 4.

**Step 4: Improvements**
In this step the teams generate and implement improvements to lower the risk of the most important relations. Here we use the Pareto principle: about 20% of the highest risk scores generate about 80% of the problems in the process. The improvements can be found in three different types:
- The frequency of occurrence can be lowered
- The process can be changed in such a way that the causes don’t have effects
- The activities to detect and resolve the cause can be improved
Step 5: Define measurements
To find root causes for problems and possible improvements, both process parameters and product characteristics should be monitored. The team should select the parameters for controlling the process. A plan is made to collect, monitor, and analyze the measurements. This is part of the control plan, a survey of all measurements in the total process. The measurements should explicitly be directed towards improving the process. This should result in a lower risk. The goal of the next steps is to make sure that the process will be in control.

Step 6: Repeatability and Reproducibility study (gage R&R study)
The team should check whether the measurements used to monitor the selected process- or product characteristics are suitable. Both systematic error and variation of the measurement should be determined. In practice the systematic error of the measurement method is often checked by calibration, but variation is often not known. Therefore a Repeatability and Reproducibility study (R&R study) is carried out and analyzed (e.g. Kane, 1989).

Step 7: Control Charts
In this phase the team should gain insight in the characteristics that can be used to control the process. The control chart should be used to achieve this. The most important function of a control chart is to detect when a process is out of control. This means that the control chart will discriminate between common causes of process inherent variation and special causes of variation. This is achieved by using control limits based on measurements from the process itself. In most cases it will concern product characteristics, in other cases process characteristics are the best parameters to monitor for disturbances in the process.

The type of control chart can vary depending on characteristics of the process and the product to be controlled. In standard textbooks often the X-R or X-s charts are suggested. However, this type of chart is often misleading because the right conditions are not present (Roes and Does, 1995). But there is a good alternative: the moving range method has shown to be applicable in many situations. Often, however, the type of chart has to be tailored to the situation with the help of the SPC-expert. For a more detailed discussion on differences in Control Charts we refer to literature (Wheeler (1991), Quesenberry (1995), and Montgomery (1996)).

Step 8: Out of Control Action Plan (OCAP)
The control chart can only become effective as a control tool when there is knowledge on which action has to be taken when an out of control situation occurs. The OCAP should provide the operators with diagnostic knowledge to determine the causes of the out of control situation and the actions to be taken to resolve the problem. Also the necessary actions to deal with the products produced when the process is out of control should be included. The target situation is to give the operators as much responsibility as possible. The use of flowcharts to represent the OCAP has shown to be very helpful (Sandorf & Bassett, 1993).

Step 9: Process Capability Study (PCS)
The Process Capability Study provides a means to measure the level of statistical and technical control of the process. In this way it can be judged whether the level of control is satisfactory to meet specification limits. If the process is in statistical control, the percentage non-conforming products can be predicted. To judge whether the process is in statistical control, recent control charts should be included. Finally, Process Capability Indices can be calculated to quantify the ratio between tolerance width and process inherent variation ($C_p$ index) and the effect on this ratio due to a deviation of the process mean from the target value ($C_{pk}$ index). For a more detailed description of Process Capability Studies and Process Capability Indices we refer to literature (e.g. Kotz and Johnson, 1993).
Step 10: Certification
In this final step the activities of the PAT and the performance of the SPC-point will be evaluated by the steering committee. A standard checklist is used to make sure that the PAT knows what is expected. The PAT will check for completeness and if necessary a brief training is organized to ensure that all operators are familiar with the implemented SPC-point. The process will be audited by a representative of the steering committee (preferably the quality manager) and the manager of the production department. The audit includes the activities on the production floor and a check on the follow-up activities by a Process Improvement Team (PIT) as described below. When the performance is approved a meeting is organized in which the PAT-members receive a certificate of their process as an official reward for their results.

In this phase, arrangements are made for maintaining and improving the SPC-point. Often the PATs are changed into PITs, which will be part of the regular organization. The task of a PIT is to continue searching for improvements, to perform regular checks of control limits and capability, and to adapt the OCAP, FMEA and process description if new process knowledge is obtained.

7. DISCUSSION AND LESSONS LEARNED

It may be clear that, if statisticians want to implement SPC in industry, they need more than just knowledge on statistical techniques. Besides experience in tailoring techniques to a specific situation, they should know possible pitfalls and how to omit them. Furthermore they should be able to translate statistical thinking into a coherent set of techniques. An implementation framework can be very helpful to achieve the above. The following organizational and methodological guidelines should be considered.

Organizational guidelines:
• Ensure management commitment
• Use phases in planning SPC implementation to take care of introduction, logical start and broadening SPC-concepts to rest of the organization.
• Set-up temporary organization structure to manage the implementation and make sure SPC becomes part of the regular organization structure after implementation.
• Monitor projects
• Make sure the concept of statistical thinking is understood and carried out in all levels of the organization.
• Appoint an SPC-coordinator, but make sure SPC does not become the work of specialists alone: the people related (especially the operators) should use SPC

Methodological guidelines:
• Provide a systematic coherent approach: integrate statistical techniques with appropriate non-statistical techniques such as FMEA’s.
• Focus on statistical thinking not on statistical techniques
• Transfer methodological knowledge
• Support in tailoring statistical techniques
• Start with basic simple tools in production before using more complex techniques such as design of experiments (in development)
• Guide organisation and teams
• Stimulate development of technical knowledge

The presented framework was used successfully in several organizations, ranging from mass-production of simple products (e.g. diodes), small batch production of various medium complex products (e.g. printed circuit boards), to low volume production of complex products (e.g. wafer steppers).
The organizational part of the framework is applicable in most organizations without large modifications. Using the four phases and the presented structure ensures management and operator commitment, teamwork and a goal-oriented project approach instead of ad hoc fire-fighting activities of one person or a few individuals.

The methodological part of the framework is more subject to tailoring due to differences in the situation. Although the functions or goals of the ten-step approach are quite universal. Tailoring the method to the processes and products involved requires expert knowledge. The assistance of an SPC-consultant is often required. However, the goal of the organization should be to acquire the necessary knowledge so that in the end, the methodological part of the SPC philosophy (statistical thinking) and the organizational part (empowerment) become part of the daily work.

literature


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