Statistical Procedures in the Course of Time

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I would like to give an overview of changes in the application of statistical procedures in industrial production over the last 30 years

Before 1980

Statistical procedures had already been applied before I started to encounter them. Here I would like to refer to the lecture of professor Masing that he gave on the occasion of the Q-DAS® user meeting on November 26, 2003. Unfortunately, this was his last public lecture before his death. The subject of his last public presentation was "Statistics as a Fundament of a Quality Method Based Way of Thinking and Acting". I would like to recommend this lecture to anyone interested in the history of statistical procedures. Find his lecture in the 5th edition of his "Handbuch Qualitätsmanagement" (quality management). It is also available as a PDF file or video on the Q-DAS® website under http://www.q-das.de/de/kompetenzcenter/masing-video/.

Professor Dr. Walter Masing

Principles of Statistical Procedures

In the middle of the 1990s the following books covered this topic in Germany:

- "Formeln und Tabellen der angewandten mathematischen Statistik" (formulas and tables for applied mathematical statistics) by Graf, Henning, Stange, Wilrich, Springer Verlag
- "Statistische Verfahren für Technische Messreihen" (statistical procedures for technical measurement series) by Dr. John, Carl Hanser Verlag.
- "Statistical Methods for Quality Assurance" by Rinne, Mittag, Carl Hanser Verlag.

These books were quite theoretical and initially hard to understand for readers from practice.

When dealing with statistical procedures in industrial production, you have to mention the American physicist Walter Shewhart. While working at Bell Telephone Company he developed statistical procedures for the evaluation of quality-related processes and applied them in practice. Thus he is considered to be the "father of SPC" (Statistical Process Control).

Walter Shewhart, born in New Canton, Illinois, on March 18, 1891; † in Troy Hills, New Jersey, on March 11, 1967

Still today both his books

- Economic Control of Quality of Manufactured Product (1931) ISBN 0-87389-076-0 or ISBN 978-0-87389-076-2
- Statistical Method from the Viewpoint of Quality Control (1939) ISBN 0-486-65232-7

provide the basis for the currently applied procedures.

While working in the ISO/TC 69 technical committee, I had the opportunity to meet Jack Kayser, the former chairman of SC 4 who had worked together with Walter Shewhart before he died.

Ford was the company to issue the Q101 quality system standard at the beginning of the 1990s. It was used for in-house productions and it applied to purchase part suppliers satisfying the demand for production parts and spare parts. Q101 included the SPC topic (Statistical Process Control) based on the theory of Walter Shewhart. An own instruction guide explained this topic

in detail. Supplementary guidelines such as "Statistical Process Control for Dimensionless Materials" or "Basic Statistics Using SAS" were accompanying documents with which the suppliers of the Ford company had to deal. Audits were used to monitor the extent to which the described procedures were implemented and applied. The application of SPC was a substantial part in the evaluation of suppliers. Ford Europe created an own position in England for the compilation and the continuous development of this standard within their company. In the 1990s, Manfred Martelock held this position.

Manfred Martelock, formerly Ford Europe

In Germany

German statisticians initially challenged SPC and its corresponding statistical procedures more strongly than in the USA. They mainly stuck to the following philosophy: "You have to adjust processes in a way that they are normally distributed and that they indicate their stability in the Shewhart quality control chart." Deviations were impermissible or had to be an absolute exception. However, this is often unrealistic or not feasible at all for various reasons. If you implement the specified procedures exactly, record the values of the characteristics by means of a measurement system, calculate the described statistics and compare them to the specified limits without questioning whether your results agree with reality, these results might lead to serious misinterpretations.

Many German companies compared their results gained according to the philosophy mentioned above with reality and had to find out that there was no agreement. As an example, they performed a 100% inspection and calculated a capability index of 1,39, but in reality they had a proportion of rejects that amounted to 10% of their production. Vice versa, they actually had a proportion of rejects that amounted to 0% of the production in a 100% inspection, but they calculated a capability index of 0,9. The discrepancy between calculated results and reality was obvious and unacceptable, so this problem caused many debates on e.g.:

- Which probability distribution does apply?
- How do we handle one-sided characteristics?
- Do the stability criteria of the Shewhart control chart also apply to not normally distributed measured values?
- Which formula is applicable in order to calculate the capability indices?
- Which limits are suitable for which characteristics?
- etc.

Since there was no answer to these questions but the suppliers were still obliged to implement SPC, they often just selected characteristics that could be shown to the customer without feeling bad about it. For this reason, the term "SPC" unfortunately became known as a "Show Program for Customers".

DGQ Sets the Course for Statistics in Germany

The German Society for Quality (DGQ e.V.) in Frankfurt strongly influenced the topic of statistics in Germany. In the 1990s, the DGQ offered the QII training, a four-week training about various statistical subjects (statistical basics, test procedures, sample systems, quality control charts and probability distribution). Rainer Franzkowski, who unfortunately died too young, was responsible for the contents of this training.

Edgar Dietrich, Alfred Schulze, Rainer Franzkowski

In terms of statistics, his approach was the ultimate solution in Germany back then. He also worked a lot in the field of national and international standardization and he participated in creating several statistical standards. At the end of his QII training, there was an exam and participants got the QII certificate. Anyone who wanted to gain further qualifications attended a one-week training in order to become an instructor. The advantage of this qualification was a broad knowledge in

statistical procedures; considerably broader than the specifications given in the SPC Manual issued by the Ford company. The correct application of statistical methods provided the answer to the discrepancy between the calculated capability indices and reality as mentioned before. However, a software based on these conclusions has not been available yet.

Even before the foundation of the Q-DAS® company, Alfred Schulze and I created software components based on general statistical basics due to our knowledge from this statistical environment. When our qs-STAT® product entered the market in 1989, there were already more than 100 SPC software programs available. These programs were offered by the manufacturers of SPC and CAQ systems and by manufacturers of measuring instruments. This variety was available for reasons of data processing. At that time the DOS operating system was the state of the art. The communication between two different programs as we know it from the Windows environment today was unusual and technologically hard to realize back then. This was the reason why the respective providers were virtually forced to have their own SPC software. The main function of this kind of software was the calculation of capability indices based on a normal distribution and the display of values in a quality control chart according to Shewhart's theory. All of them complied with the guidelines of the Ford company, however, none of them provided any answer or solution to the problems described above.

Q-DAS® Enters the Market

We offered a wide selection of statistical procedures in qs-STAT®. Consequently, be it machine acceptance or long-term studies of processes, we were able to provide the statistical procedures for the real situation leading to traceable and correct results in practice. Here are two typical examples:

- One-sided characteristics tend to be not normally distributed due to their physical properties (typical examples are form and location parameters and coat thicknesses). Thus you cannot use a normal distribution in order to determine the capability indices. Only unimodal skewed distributions provide realistic capability indices, such as the logarithmic normal distribution, Pearson or the Johnson transformation.
- In case of tools including several cavities, the variation of the parts within a cavity is normally relatively small; however, the location of the respective cavities strongly differs due to manufacturing tolerances. Thus it is not possible to use any Shewhart chart in the classical sense. The same applies to the calculation of capability indices. In order to be able to calculate realistic capability indices in these situations and in order to monitor processes by means of reasonable control limits, Q-DAS® refined the mixed distribution and the Shewhart charts by means of extended limits.

When we presented our software in seminars and at the plants of our major customers, the participants quickly realized that this tool provided the correct answers to the questions that have not been solved yet. This fact raised the acceptance of the SPC application. During the following years, our conglomerates created more and more guidelines hence including the functionalities offered by Q-DAS.

Ford Develops Software Test Examples

Even Ford quickly realized that the people's believe in the correctness of everything a computer does - which was quite common these days - was inappropriate for the application of SPC. The SPC systems of various providers available on the market back then could not describe the actual state of a process run correctly and without restrictions. However, the release of the supplementary Ford guideline "Process Capability Studies" provided the basis for calculating significant and correct capability indices even in case of not normally distributed process results. Together with the Ford test examples, which had been developed by the Q-DAS® company and Mr. Martelock in his position for Ford Europe quality methods, it became easy to evaluate whether SPC systems were qualified for the intended purpose.

The test examples are datasets describing different process types or process situations. By loading the published test data into the evaluation software you want to test, you just have to compare the numerical and graphical results in order to verify the qualification of the evaluation software. Since Q-DAS® helped to develop these test examples, the use of these examples increased the Q-DAS® brand awareness in Europe by leaps and bounds. All producers of SPC systems now had to provide evidence that they implemented the test examples correctly. For the calculation of capability indices in case of Ford purchased parts, neither Ford nor their suppliers accepted software producers who were not able to prove that they passed the test. Correct calculation results, significant graphical displays and, of course, a user-friendly handling laid the foundation to extend the newly attained qs-STAT brand awareness even further through excellent performance.

Hartmut M.W. Nowack Provides the Evidence

Since 1998, Hartmut M.W. Nowack of the Mercedes Car Group has been in charge of a representative study including more than 1000 different process situations. He obtained the respective files from different companies and from different applications. The detailed analysis and evaluation of the files showed what our gut feeling already indicated: Only 2% of the processes are nor-

mally distributed and stable according to Shewhart quality control charts.

Due to the tools and statistical procedures of Q-DAS® implemented in qs-STAT® we were able to describe and evaluate the major part of all processes correctly. The results we gained were the quality capability indices C_p and C_{pk} as well as P_p and P_{pk} that were close to reality. The relation between theory and practice became comprehensible.

Hartmut M.W. Nowack

Uniform Data Format Leads to the Efficiency of SPC

At the beginning of the 1990s, computer systems changed from DOS to Windows. This was a big challenge for many software houses since the Windows operating system demanded different developments from software engineers than DOS had done. In addition, Windows provided the option to start and run several programs at the same time. Since many producers of SPC systems did not want to make the effort to port their software from DOS to Windows and since the qs-STAT® brand awareness continued to rise, many producers decided to cooperate with Q-DAS®. Instead of developing their own software, they recommended qs-STAT® as a software package for statistical evaluations to their customers or even integrated qs-STAT® into their own software.

The communication between the third-party system and qs-STAT is based on the Q-DAS® ASCII transfer format that was initially developed by Q-DAS® together with conglomerates such as the Mercedes Car Group or Ford. Today this data format is an international standard for the exchange of quality information. Several companies have made this format their standard and still maintain this standard. Today this data format is referred to as AQDEF (Advanced Quality Data Exchange Format). Please find more information about this format on www.q-das.de in the "Service" section under "Data format".

Q101 Becomes QS-9000

In 1994, the so-called "Big Three" (Chrysler, Ford and General Motors) published the Quality System Requirements QS-9000 standard in the USA. These requirements only included the application of SPC and MSA since the implementation of these procedures was already described in the reference manuals "Fundamental Statistical Process Control" and "Measurement System Analysis". Particularly the SPC Manual was widely based on the Ford SPC standard. The MSA Reference Manual was a newly created standard which was considerably more comprehensive than the MSA guidelines of the Ford Company. After the release of QS-9000 at the end of the last century, suddenly all suppliers of Chrysler, Ford and General Motors were forced to arrange their quality management system accordingly and to meet the demands specified in the SPC and MSA manuals.

Q-DAS® Automates Evaluations

Q-DAS® met the described requirements in qs-STAT® (for SPC) and in solara (for MSA); moreover, we provided further helpful statistical functionalities. A distinctive characteristic was the automated evaluation. Q-DAS® combined and linked different statistical procedures in a way that made it possible to automatically determine the suitable distribution model and the appropriate quality control chart including the reasonable formulas for the calculation of quality capability indices only by analyzing the dataset. This raised the acceptance among many users to apply statistical procedures. From now on, you only had to record the data, transfer them to qs-STAT®, evaluate them automatically and eventually display the results. As a result, the only task left to the user is to interpret the results without knowing in detail the statistical procedures that are hidden behind it. Since Q-DAS® already provided their software in more than 15 languages at the end of the 20th century, we already set the stage for the international distribution of our software.

ISO/TS 16949 Develops

At that time, the suppliers of the automotive industry did not only have to deal with QS-9000 but also had to satisfy the requirements of national associations, such as VDA 6 in Germany, the CNOMO standard in France or the specifications of the ANFIA in Italy. Suppliers had to accept the challenge to meet the quality requirements of the respective customer. For this reason, a Task Force of the automotive industry developed ISO/TS 16949 which was referred to as "Quality Management Systems – Particular Requirements for the Application of ISO 9001 for Automotive Products and Relevant Service Part Organizations".

Nowadays, this technical specification is obligatory for any supplier in the automotive industry and must be implemented in each company. ISO/TS 16949 combines different existing quality management system requirements (mainly of the North American and European automotive industry). The SPC and MSA requirements contained in ISO/TS 16949 are broadly defined. For this purpose, the VDA 6 catalog was created for German automakers. Possible statistical procedures are assem-

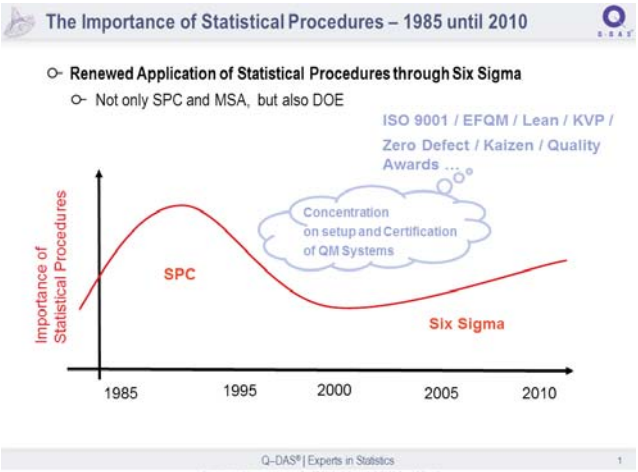
bled in ISO/TS 10017. However, it is required that these instruments are used. You will have to provide evidence thereof in a system audit. ISO/TS 16949 leaves the reference manuals used in each individual case up to the respective applicant. You might either user the company guidelines of conglomerates or the SPC Manual of the AIAG. In case of the German automotive manufacturers, the VDA Volume 4 and the VDA Volume 5 or the 4th edition of the MSA are used for capability analyses of measurement processes.

The Ups and Downs of Statistical Procedures

Statistical procedures certainly had their high point during the introduction of SPC at the beginning of the 1990s. The number of participants who attended QII training (see annual report of the DGQ) is a good example to prove this fact. However, the more companies dealt with the implementation of their quality management system based on ISO 9001 or later ISO/TS 16949 or QS-9000, VDA 6 etc. during the time in between, the more the meaning of statistical procedures faded into the background. People thought that sufficient preventive action is enough to control processes in a way that all quality requirements are met. However, this proved to be a mistake.

Systematic improvement of products and processes came to the fore more and more.

For this reason and particularly because of the introduction of Six Sigma at the end of the 20th century, statistical procedures gained in importance again, i.e. people started to focus on the real process again. By realizing projects based on the DMAIC 5-step approach (define / measure / analyze / improve / control), the classical methods like SPC and MSA were applied more frequently again. The improve step additionally contained the design of experiments subject including test planning, regression analyses and analyses of variance. In addition to the DMAIC approach in order to improve



existing processes by means of projects, the DFSS topic (Design for Six Sigma) for the development of new products and processes has been put forward over time. Even this methodology required statistical procedures

National/International Standardization of Statistical Procedures

At ISO, the Task Committee TC 69 is responsible for standards on statistical topics. The corresponding mirror committee at DIN (German Institute for Standardization) is the NA 147-00-02 AA committee (known as NQSZ 2). The ISO/TR 13425 technical report describes all statistical procedures with which TC 69 deals. Find an overview of those standards on www.q-das.de under "Competence Center Statistics" – "Norms and Guidelines". I would also like to mention the ISO/TR 13007 technical report. It explains a total of 12 typical statistical procedures in short. Moreover, it illustrates typical applications and points out the limits of these procedures. In terms of SPC and MSA, standards were only created during the last 10 years. With the exception of two standards about quality control charts (Shewhart control charts and acceptance control charts), there were hardly any activities referring to this application area in the field of international standardization. Furthermore, it takes a long time to create an international standard. A standard that takes only two to three years to be released are considered to be a very quick development.

In the meantime, several series of standards have been developed covering topics such as QM systems, SPC, MSA and Six Sigma:

- ISO 7880 et sq. about quality control charts
- ISO 14253 et sq. about machine and process capability
- Part 7 about measurement process capability analyses
- ISO 13053 et sq. about Six Sigma.

Statistical Procedures in the Future

Due to the software packages available today, users have to expect a black box in terms of statistical procedures. Users are responsible for recording and exchanging data by means of this black box. The black box can be configured in a way that it adapts to the respective corporate requirements taken from guidelines and that it makes evaluations based on these specifications. The main benefit for users is that they are able to create the desired statistics, to interpret the statistics, in particular, and to take corrective action, if required. This applies to the SPC subject area (primarily quality control charts and capability indices) and to the MSA Measurement System Analysis subject area when purchasing new measuring instruments and in continuous inspections while using the measurement systems. The application of a validated software is indispensable since the valida-

tion is required in order to accept statistical evaluations as trustful. Especially globally acting conglomerates will then be able to use this software worldwide in the respective plants and feel certain that the calculations are based on the same principles. Particularly by standardizing reports and output masks the communication between departments, divisions and plants will become easier. Notably benchmarks will be simple to create. Everything that is valid and binding within a company and its plants can also be transferred to suppliers. It is of utmost importance to set a high value on traceability. In case of any problems with products or components occurring today, the responsible supplier must be able to trace back where the problem is caused in his supply chain. The problem will be detected quickly and trustfully if supplier and manufacturer use the same calculation procedures. The results become transparent and traceable for all parties involved. Standards considerably support you in doing so.

Especially in medical technologies, the requirements based on the quality system of the FDA (Food and Drug Administration) are very high, particularly in terms of the convertibility of data and evaluations. We have to expect that one day these requirements will also apply to the environment of the automotive industry.

Due to statistical procedures, the tasks of the users are restricted to the following:

- They know the procedures, their fields of application and their meaning.
- Then they are able to interpret and evaluate the results and they are able to make the required decisions.
- The information system prepares the results according to the respective task and in a user-friendly way.
- The information is communicated in a dedicated manner in order that, on the one hand, the respective user of the results cannot put too many information into the results and, on the other hand, the user does not miss any information.

I will be pleased about any recommendations, suggestions and questions about this article. Please write an e-mail to Edgar.Dietrich@q-das.de.

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