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## **INTRODUCTION**

At present, a market trend can be observed for the emergence of new enterprises characterised by a very large volume of production of a narrow range of products, using modern, high-performance technologies. With a large scale of production, it is not possible to completely eliminate products that do not meet the high quality criteria, however, it is necessary to reduce the number and probability of their occurrence, and to detect them at an early stage of the production process, which can be achieved by using appropriate statistical methods of process control based on the analysis of collected data (Kempa, 2011). Statistical methods of process control are based on Crosby's zero defects principle, which claimed that reliability and high production efficiency can only be achieved by eliminating errors and defects at all stages of the process. The main assumption of this principle is to eliminate the causes of non-compliance, not just their effects. For this reason, the main focus should be on ensuring quality at the source, by the earliest possible detection and elimination of a defect or problem. The author of this principle assumed that as a result of detecting nonconformities in the next stage of the process, the cost of this defect increases tenfold in relation to the previous operation, and determined that this goal can be achieved by empirically measuring the level of process quality and presenting the results in an easy to interpret form, which allows for effective corrective actions in a short time (Hamrol, 2005). One of the fourteen Deming's principles also directly refers to the necessity of using statistical tools to control processes, instead of quality control of all products, because the quality of final products is primarily based on the quality and stability of processes (Montgomery, 2012).

## **CAQ systems**

Computer-aided quality assurance (CAQ) is a class of applications aimed at the inspection of the quality of products, using, among others, tools like: goods inward inspection, statistical process control (SPC), management of measuring equipment, suppliers rating and attribute charts (Kent, 2017).

In the last decade, one can notice the significant dissemination and development of

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CAQ systems. There are many CAQ applications on the market, of which only a few offer the full expected set of functions, including (Lixandru, 2016):

- the ability to implement a wide range of modules to support the functioning of key processes of the quality management system,
- full integration of all functional modules of the CAQ system,
- central supervision of the activities of all management system processes,
- the ability to adapt individual modules of the universal program to specific industry branch requirements, especially in relation to the new standard of the quality management system IATF 16949: 2016,
- meeting the SPC requirements, including the ease of data analysis and automation of response plans,
- the possibility of implementing in many company's facilities (e.g. of a global company), including a single, global database.

The main benefits of applying CAQ systems solutions in manufacturing enterprises should include (Lixandru, 2016): reduction of operating costs, facilitating business management – reduction of human resources necessary to manage the management system, the ability to analyze data in real time, high speed of historical data analysis, process control with the possibility of quick response and removal of causes of emerging problems, raising the level of quality and level of customer satisfaction, as well as ensuring data security.

### **The purpose of statistical control of production processes**

Statistical process control (SPC) refers to quality control of processes using statistical methods, in the scope of ongoing process control, used to detect possible process disruptions and to confirm continuous improvement of its quality by taking appropriate corrective actions (Azizi, 2015). Each process (production or business) is characterized by volatility. This variability results from many factors, that can be internal or external. The production process as part of the system should be considered in the category of "black box" in which the transformation of inputs (X) takes place, which take the form of controlled factors in outputs (Y), which are the response to the set level of input factors. Each process is subject to the influence of uncontrolled factors in the form of disturbances, which have the character of random noise. SPC is a tool allowing to monitor whether the process is statistically controllable (predictable in its behavior) and to distinguish the disturbances that occur in it (specific reasons – "signals") from the natural variability of the process (random reasons – "noise"). The use of SPC allows to define when corrective actions should be taken, and when to improve or leave the process without interference, to avoid the so-called "Over-regulation phenomenon" (Purushothama, 2010).

As part of the application of SPC, the following issues are analyzed in enterprises (Deming, 2000): with what dispersion of the measurement results the production process is performed (process stability – so-called "Predictability") and what is the ability of this process to meet the requirements of the specifications (process quality). The term SPC should also be understood as a comprehensive system of orderly monitoring of the currently achieved quality of production, carried out in a systematic manner, in order to achieve the following objectives (Montgomery, 2012):

- improvement of the quality of processes and products manufactured,
- increasing process efficiency, including by reducing the time spent on control operations,
- reduction of waste and reprocessing operations – by reacting quickly to noticed special causes in the process, resulting in "out of specification" products,
- reduction of inspection costs – by extending the frequency of control of a specific characteristic based on data from the process and analysis carried out,
- quick response and problem solving by production workers during the process,
- providing employees with information on the process and phenomena occurring in it, e.g. concerning the frequency of tool wear,
- introduction of systematics in the process regulation by applying rigid rules of the possibility of interference in the process by machine and device operators,
- using a common language in the company, used to describe and prioritize processes,
- distinguishing the causes of random and specific variations.

### **Main SPC tools**

The majority of commonly used tools for statistical process control was established in the United States in the early 1920s, during the period of intensive development of mass production. Due to ease of use and simplicity, these methods have found recognition in other branches of the economy. The SPC tools include (Deming, 2000):

a) Shewhart control charts – derived from the name of the American engineer W. A. Shewhart, who proposed the use of such methods for economic quality control. The basis for developing this tool lay in the fact that there are no two identical products, because each process from which they derive is accompanied by two types of variations occurring over time:

- random causes (affecting all products from a given production process and occurring in the form of noise, e.g. changes in ambient temperature or stiffness of the machine); they are treated as a natural element of the process and state about 85% in the total causes of process variability, if the production process is only affected by interference in the form of noise, it can be stated that it is predictable and statistically controllable,
- special causes that appear sporadically in the production process and have a major impact on some of all manufactured products; they cause significant changes in the process, being responsible for about 15% share in the total causes of process variability; if the production process is subject to special causes, it must be stated that it is characterized by unpredictability, it means it is statistically uncontrollable.

The use of control charts in the scope of controlling the production process creates the possibility of detecting and analyzing the impact of both types of variability on the process.

b) Process Capability ( $C_p$ ,  $C_{pk}$ ) and Process Performance ( $P_p$ ,  $P_{pk}$ ) indicators/indexes – used for numerical evaluation of process quality. They illustrate, by means of value, the relation between the "customer's voice" expressed by the product specifications (tolerances  $T$ ), and "the voice of the process" expressed by the process variation (standard deviation  $\sigma$ ).

Currently, the use of this type of quality management tools has become a common standard among companies producing a narrow range of products in large volumes, in particular in the automotive industry, which fundamentally bases meeting the requirements in the monitoring of production processes on them (Purushothama, 2010). In the case of production process control using statistical control tools, in which each stage is supervised for stability using control charts, if signs of deregulation are observed, actions are taken to eliminate potential causes.

Then, based on the collected data, the process quality is assessed using the process capability indicators. If a given process does not show the required level of capacity, then systemic (improvement) actions are taken. If every stage of the production process will be statistically settable, it can be stated with a certain probability that finished products will be compliant with the client's requirements with acceptable scattering (variability between the results of subsequent components, within accepted tolerance) (Kent, 2017).

### **NORMATIVE REQUIREMENTS IN THE STATISTICAL PROCESS CONTROL**

The constantly growing expectations of automotive industry customers force the companies participating in the supply chain to implement and/or adapt statistical control methods to the required standards. For this reason, requirements in the field of quality management systems in the automotive industry (e.g. IATF 16949:2016 – Quality management system requirements for automotive. Production and relevant services parts organizations) related to monitoring and measurement of manufacturing processes, force producers to use appropriate methods and tools that will allow them to demonstrate the ability to achieve their goals (IATF 16949, 2016). If the goals are not achieved, it is necessary to make immediate corrective actions and long-time changes. For example, in accordance with the requirements regarding the ability to ensure the quality of supply defined in volume 2 of the VDA standard – Ensuring the quality of supply, approval of the production process and product (PPF), in the case of failure to provide proof by the company in the form of indicators on the characteristics of special processes (eg. for welding operations, heat treatment), supplier is forced to obtain it, based on correlated secondary characteristics, or perform 100% non-destructive inspection of products (Reid, 2002).

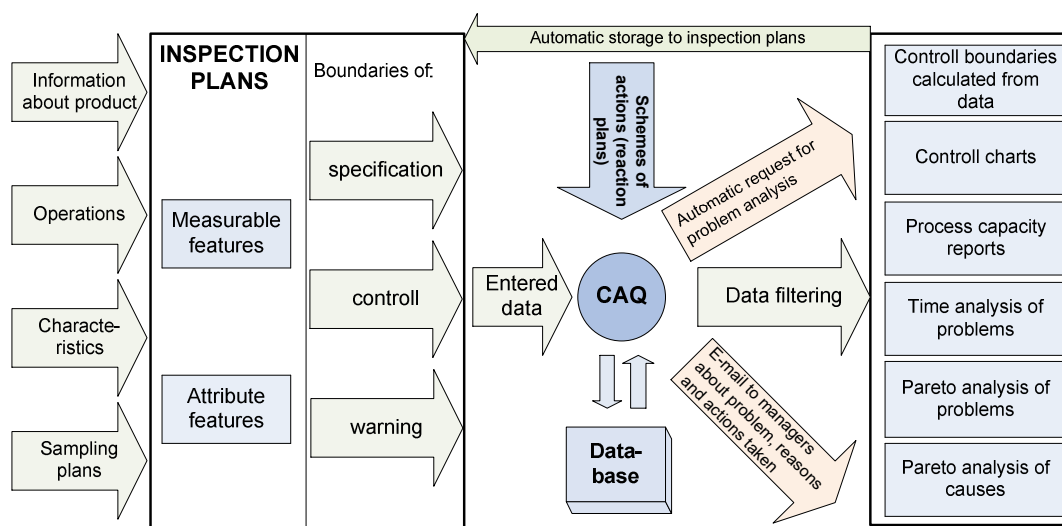
Manufacturers are obliged to maintain the capacity and results of the production process in accordance with the requirements set by the customer, with the preservation of specific measurement techniques, sampling plans, acceptance criteria, response plans and, which are new requirements with respect to the previous technical specification ISO/TS 16949:2009 (Quality management systems – Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations), used in the automotive industry – records of the actual measurement values, as well as escalation processes in the event of failure to meet the acceptance criteria. In addition, all special events, such as changing tools or repairing machinery, must be recorded and stored in the form of documented information (IATF 16949, 2016).

In some cases producers, when trying to apply statistical methods of process control, do not take advantage of the value they bring with them as an important factor in improving quality (Lixandru, 2016). It is not uncommon, that even after the implementation of SPC, companies place the main emphasis on graphical data

presentation in order to maintain cooperation with clients in the automotive industry, and not to improve the actual quality of processes. For this reason, it should be borne in mind that the effectiveness of implementation and use of SPC is demonstrated by the results of the activities undertaken. In addition, a very important factor in the effectiveness of using statistical methods to control the quality of processes, is the development of awareness of the existence of this tool and the display of the benefits of using them in an appropriate manner for the entire staff of the organization.

### STATISTICAL PROCESS CONTROL USING THE CAQ SYSTEM

Information resulting from analysis has critical importance in supervising and improving production processes, it's an important element deciding about the company's competitiveness. The CAQ system enable an easy and quick analysis of statistical results and creation of reports from previously registered production data by providing access to related data, tools for efficient and quick processing and the possibility of clear presentation and distribution of results. Typical CAQ system enables the user to choose at any time the selected data range, based on time, production line, parameters, obtaining results referring to a specific production area and product (Fig. 1).



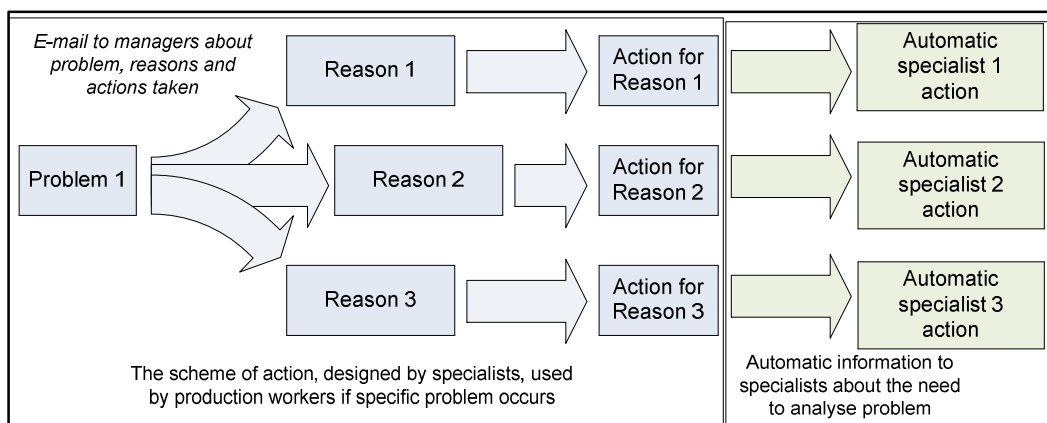
**Fig. 1 CAQ system in the production control and data analysis**

The way of data recording in the CAQ system ensures the recording of results in real time. This means that when a new value appears, it is:

- saved in the database,
- included in the statistical calculations,
- put on appropriate cards,
- analyzed for compliance with the requirements: limits of control, specification, warning and statistical rules (e.g. 7 consecutive results of measurement above or below the average of typical previous results or 6 consecutive ones in an ascending or decreasing trend).

The requirements concerning the data recording module in the CAQ system are (Azizi, 2015):

- easy method of entering data – the entered measurements are presented in the form of a table, and, for better orientation, on the control chart, which also contains the values of control limits. Colouring (green/red) instantly informs the operator about the status of the entered value and such events as: exceeding the control limits, error of entry, occurrence of trend, etc., are signalled,
- possibility of analysis of measurement results on control cards,
- automatic calculation of control limits based on real data from the process, which can then be recorded in the control plan and used on the control chart during the analysis of subsequent results,
- automatic calculation of process capability indicators and generation of a readable capacity report along with a histogram or Gaussian curve and a control card,
- online access to audit documents, such as inspection plan, control instructions,
- the ability to register problems, their reasons for occurring and corrective actions taken to eliminate them – this is a tool allowing to conduct a cause and effect analysis for detected non-conformities of the tested product feature. It is automatically triggered when the control limits or the tolerance limits of the measured characteristics are exceeded. The production worker has to select from the list the problem that appeared, the reason and confirm the implementation of the recommended action. The actions taken are saved in the database, and on their basis it is possible to analyze what problem most frequently appeared for a given product, how often and what reasons caused it (Fig. 2).



**Fig. 2 The structure of cause and effect analysis in the CAQ environment**

### The LEAN-QS CAQ System

One of the CAQ applications available on the market is the LEAN-QS program, which is offered by the Lean-Soft, specializing in comprehensive solutions in the field of information and business technology, used in business activities in accordance with the Lean Management philosophy. The offered products, as well as the adopted management strategy, should allow to meet the expectations of customers and enable individual adjustment and changes in the functional scope, in order to optimally adapt to the specific requirements and expectations of clients. LEAN-QS is characterized by (Lean-Soft, 2019):

- the possibility of being implemented on an international scale due to the availability of various languages of program support, such as Polish, English, German, Italian and Czech,

- basing on the guidelines of AIAG Core Tools manuals,
- an advanced mechanism of monitoring the timeliness of tasks and activities under the management system,
- integration with e-mail, active directory, MS Office programs,
- support in the supervision over the implementation of key processes under ISO 14001 and ISO 45001,
- enabling data import to administer the system from .xls files and integration of databases,
- the possibility of using the free Firebird database or the Microsoft MS SQL Server database.

### **Insights related to the practical implementation of the CAQ system**

An important advantage of the CAQ system is the ability to automatically generate tasks for specialists (engineers) to accurately analyze the observed problem of exceeding the control limit for a key parameter and to send information immediately by e-mail.

However, observations carried out in many enterprises indicate that due to the need for knowledge, funds and resources for implementation and supervision of SPC/CAQ, standard Microsoft Excel software is often used instead of specialized tools, in which control charts and sheets analyzing the process's capability are developed together with a database to analyze the quality of processes over time. In the same way, catalogs of non-compliance (errors) and rules of conduct in the case of detection of instability of processes on control charts are prepared.

The disadvantage of this kind of solutions is the need to rely on the high awareness of employees and the reliability of the data they register with the required fixed frequency. In addition, support for this type of tools using conventional solutions requires the involvement of a large number of mid-level employees in order to provide control charts for production and to develop analytical sheets and calculate control limits together with the analysis of process quality over time. Such sheets must be validated for correctly obtained results based on previously prepared formulas. It is a common practice to use the data in the examples in the SPC manual developed by the AIAG to compare the results. Data from such validation for own analysis sheets must also be kept (IATF 16949:2016, 2016).

It takes significant time to rewrite the data recorded on the control charts from the current production to the previously created analytical sheets in order to calculate the process capability indicators together with the analysis of the data distribution. This generates delays in data analysis until they are entered into the system. There is also a high risk of mistakes when rewriting results into electronic forms. In addition, there is no possibility of quickly comparing data in the long term, e.g. year to year, as it requires additional and time-consuming data processing.

The ISO 9001:2015 standard (Quality Management Systems – Requirements) in clause 7.5.3.1 requires adequate protection of records, in the form of documented information, due to protection against loss of confidentiality, improper use and loss of integrity. In addition, point 7.5.3.2 of ISO 9001: 2015 requires the proper storage and protection of data against unauthorized access (EN ISO 9001:2015, 2015). Therefore, only a few people could have access to the created analysis sheets and would often

have to back up all data obtained from the process.

From the point of view of the requirements of standards for the quality management system and one of the two main assumptions of the SPC, it is necessary to use response plans, which in conventional form must be based on the reliability and responsibility of the personnel supervising the production process in terms of their correct selection, performance and leaving the record as proof from carrying out the inspection. Unfortunately, in this form, the senior management is unable to quickly analyze the most important problems and causes that are repeated chronologically using tools such as the Pareto-Lorenzo analysis.

### ANALYSIS OF THE EFFECTIVENESS OF AN EXAMPLE CAQ SYSTEM

As part of the conducted research, a comparative analysis of key qualitative indicators was performed in two plants (Plant A and Plant B) of the same company in the same period of time. Both plants carry out the heat treatment of the same product family and are suppliers for the same customer, therefore the products delivered were subject to the same requirements ( $P_p/P_{pk}$  min. 1.33, PPM max. 100,  $Z_{bench}$  min. 4).

Plant A uses the CAQ system (LEAN-QS program) from January 2015 for the ongoing analysis of process stability over time, based on the control limits and evaluation of the process's ability to meet customer requirements, while reacting quickly to process instability signals (by applying adjustments to parameter settings the process). Plant B uses conventional tools for collecting and analyzing statistical data, including: spreadsheets developed in Microsoft Excel), based on specification limits. Table 1 presents selected quality indicators for plants A and B for the first 4 months of 2018.

**Table 1**

**Comparative analysis of selected quality indicators for the first four months of 2018**

Selected quality indicators	Plant A	Plant B	Difference
$P_p$	1.64	1.46	0.18
$P_{pk}$	1.44	0.92	0.52
PPM	7	3014	-3007
$Z_{bench}$	4.33	2.75	1.58
<b>Costs of the inappropriate quality [PLN]</b>	10842	41898	-31056

Plant A shows significantly higher quality indices, directly related to the process's capacity, than plant B. The use of constant analysis of process capacity over time and the implementation of improvement projects has caused that the probability of occurrence of an incompatible unit expressed in PPM in plant A is over 3000 PPM lower than at plant B. Compiled results (Table 1) confirm the effectiveness of the adopted solution in the form of a CAQ system. It can be stated that the increase of quality indicators for the analyzed production processes, as a consequence, translates into savings in the costs of lack of quality incurred, which in consequence is associated with achieving a high level of customer satisfaction.

### CONCLUSION

The current requirements of standards for quality management systems as well as additional specific industry requirements and expectations of customers in the scope of effective monitoring of production processes for mass production, force suppliers to use effective quality control of product samples based on statistical process control (SPC) assumptions.



Bearing in mind the long experience of software producers in the development of CAQ systems, with particular emphasis on meeting the requirements of the automotive industry and relatively low implementation costs, taking into account the software and IT infrastructure alone, this is the only tool for supporting the main process tested for efficiency, which can't be anymore replaced with conventional tools such as network drives, mailbox, Microsoft Word, Excel, even with the allocation of a large amount of human resources involved in handling this process.

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**Abstract.** The aim of the article is to present the case study of implementation of the example CAQ system, which allows to meet the requirements of IATF 16949:2016 and the VDA 6.1 standards in the field of statistical process control (SPC). The foundations of the CAQ systems concept and their specific requirements, especially for companies operating in the automotive industry, for which modern CAQ tools are necessary, in the described case based on the LEAN-QS program, are presented. The article presents the observations and results of the analysis of the operation of the quality assurance system in a company that is a supplier of car parts. One of the modules of the LEAN-QS program was implemented there, which makes it possible to meet the requirements of a certified quality management system. The effectiveness of the presented tool was demonstrated, allowing to meet industry requirements while minimizing resources necessary for supervision and proper implementation of the quality management system process, which in this case is the SPC.

**Keywords:** IATF 16949:2016 standard, VDA, SPC, CAQ, automotive industry, process stability and capability, control chart