A MODEL OF PLANNING AND OPERATION OF THE NATIONAL QUALITY SYSTEMS

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Abstract

The study gives an overall picture about the basis of the statistical process improvements taking into account the Hungarian features. After a theoretical introduction about the variations in the processes the different generations of the quality control are shown. Then the topic of controlled and capable processes is discussed and finally the suggested way in Hungary is explained. The study uses several cases from the Hungarian industrial sector in order to visualize the theoretical statements.

Keywords: quality, system, control, variation, methods.

The famous prediction of Juran forecasting that the 21st century will be the century of quality, becomes reality also for us confronting with requirements and practices of the European Union.

It can be observed and because of the openness more and more of us can experience personally that there are other quality and quality management principles, approaches, practices, models and methods in the developed social and economical regions of the world (like North-America, South-Eastern Asia, Western-Europe) than those which were used in Hungary in the previous half of century.

These principles, approaches and the continuously widening toolbox of the models, systems and methods are known. I think that based on the last decade Hungarian and international experiences, several national and international projects, many quality management system implementations, research and teaching experiences and some failures one of the most critical differences between the mentioned regions and Hungary is the 'quality of adaptation'.

The hundred-year history of the modern quality systems, the different and similar elements of the sharply separated three quality schools (Japanese, American, European) [1] inspire to find such a model and model management (model operation?) which can be adapted to the national circumstances but fits to the guide-lines of the these schools as well as help us to guide our quality systems including the business, social and political participants to the European requirement system of the third thousand years.

It is evident that there is one way to the quality in the competitive circumstances and this is the quality management system. A considered system-wide model(s) can be the long-term solution because it is the only possibility to produce products and services on constant quality and ensure the efficient and economical operation in the same time [2] [3].

The hundred-year development of the quality systems leads from the endproduct check to the TQM (as a 'system management approach in management environment') [4]. The real question is the way itself.

The study describes the practical realization of this way which aims the TQM as a strategic, system-level purpose and the controlled processes and system as a tactical, operative-level purpose [5] [6].

It is possible to get from the general Hungarian state to the stable operation of such a system through several-year systematic work. Some elements of this process are demanded by the ISO 9001:2000 standard but the TQM centered operation requires a long-term project. The PDCA-based structure of the ISO 9001:2000 and the continuous improvement activity in line with that as well as the last two principles of three ones of the TQM (customer focus, process improvements, empowerment and total involvement) appoint the same methodological direction: practical system operation and continuous improvement. Our experience is that moving toward the TQM from the current state is possible on a definite way which is shown step-by-step in *Fig. 1*.



Fig. 1. Realization pyramid of a system moving toward TQM

The figure presents that two 'floors' should be built before reaching the controlled and capable processes. This study deals with these issues only that extent how it is required to the well-established discussion concerning on the level of the controlled and capable processes.

On the first level a reliable data and information background should be formed in order to ensure the required density and quantity of data for the evaluations. The detailed expression of it was worked out in several publications (e.g. [7]), here some important points should be stressed.

The first one is that this level means not only the types of the data and information but also the methods for collection, storing, processing and assessment of those. A consequence of it is that the dynamic assessment methods should be preferred to the static ones. (E.g. deviation indicators instead of averages; flowcharts and logical schemes instead of simple diagrams; teamwork instead of problem solving by individuals and experts.)

The second important point is the transformation of data and information from the passive features (reactive, inspection-centered) to the active ones (planned, inprocess analyzed).

Operating of controlled processes needs active data and dynamic methods.

Effective failure analysis and reduction actions can be implemented on an established data and information base.

It is possible to perform efficient failure analysis and improvement actions based on these data and information. This is important because the controlled processes are worth the efforts only in case of low failure and non-conformity level. It is necessary to refer them to two aspects.

First of all we would like to take the notice that the efficient failure analysis requires the application of the combination of known tools and methods (like TIPHIB, ABC-Pareto, FMEA, Ishikawa-Cause/effect-diagram) according to the given problem instead of using these tools separately (e.g. discovering the typical failures with TIPHIB because of the not-known background, then using FMEA weighting, finally working out Ishikawa diagrams for the most critical problems). [8]

The other less stressed area of the failure analysis is the grouping of the failures, their modes, factors and noises which have any effects on quality as well as the fact that the different failure groups should be handled by different people on different ways and times.

The failures, modes, factors and noises which impact on the process (quality) may be separated into more groups taking into consideration their features, the necessity and possibility of influence as well as the methods. Since the separation of these noise (or failure or mode) factors is significant for the sake of efficient failure analysis and improvement the rating of the impacting factors and failure modes should be done before the analysis both the passive and the active data and information base.

In many cases the unclear combinations of these groups result in difficulties of the cause \rightarrow effect analysis and working out and application of the cause \rightarrow impacting \rightarrow control chain.

The impact of the common causes of variation is usually slight on the process and the quality parameters so they have influence on the system state and the set level to a less degree. Therefore, it is not possible and is not necessary to deal with their control.

However, the usual characteristic of the processes and systems is that they are influenced by many common causes and noises which balance the effects of each other. In the practice if only these causes have influence on the process (or only they are examined) the central distribution stands out: the result of these factors is a normal probability distribution. In this case the process or quality parameter follows a normal distribution around the expected value (at controlled processes: the set parameter value).

Therefore again it is not possible (because of the many little impacts) and is not necessary (because the target value is the expected value) to deal with their

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control.

Of course the deviation of the common causes may vary a lot and it is not sure that the process and product quality specifications are fulfilled. If the range of the common causes is significantly larger than the required specification range the deviation of the system or process or product quality parameters should be reduced.

The reduction of the range of the common causes worth the efforts only on long term. It is also true in general that the reduction of the common cause range is harder than that of the dangerous causes from the point of both the professional aspects (mapping and assessment of causes, cause systems, effects, etc.) and the resources (time, financial, human, etc.).

The knowledge about the range and deviation of common causes is a key issue when striving for controlled state because that determines the possible degree of the controllability of a certain system in a given moment. This is also a reason why the separation of the various causes (common, dangerous, sporadic) is so important. The quality capacity level and its reserves [9] can be defined only in this way and it has essential impacts on the quality improvement project planning, steps, actions and the methods to be used.

The other main causes are called sporadic ('systematic') which are variations with a deviation for a long time.

In opposite with the former group the feature of these causes is that the occurrence of them has a dramatic effect on the process and results in an uncontrolled state. Therefore, their knowing and elimination are basic for the appropriate process and quality parameters.

There is a significantly negative impact of the sporadic causes and those change the parameters to be controlled. However, it is important that a well planned quality improvement-development-assessment system can help to recognize these problems immediately. The second-level β -mistake cannot be avoided in hundred percent in any system!

Fortunately, in case of well planned and managed quality systems the number of the sporadic variations is much lower than that of the problems because of common causes. Therefore, it is not only necessary but also possible to deal with the sporadic causes as the effect \rightarrow cause \rightarrow acting chain can be really assessed.

The sporadic causes which move the set level and the mean value should be eliminated immediately or on short term. It also can be stated that the analysis of the background of these causes is simpler comparing with the common causes.

The 'dark horse' of the variations is the special ('dangerous') causes.

The main feature of these causes is the capriciousness: they occur on ad-hoc way. There are no such causes at a given process for a long time but they can appear at unexpected periods and situations. The dangerousness of them is shown by the characteristic that they often disappear very soon before the real assessment and isolation. The impact on the product parameters might be discovered later e.g. during the use by the customer. The dangerous variations usually result in the tremendous change of the process parameters while the experts, operators, etc. do not understand the real reasons of it. In many cases the process has to be stopped immediately.

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Usually, the analysis of the dangerous variations should be delayed and it is possible, necessary and worth to assess those only on mid-term.

In general, we can state that discovering, analysis and impacting possibilities are also very extreme. The root cause of them may be a people mistake, a moment trouble in the system operation, short uncontrolled state (e.g. electricity shut-down, foreign material, some 1/100 sec. delay of an automatic unit, line break-down because of a jammed part, etc.). These root causes might be discovered through long and hard professional analysis.

The following chart shows the appearance of the common/sporadic/dangerous causes through a critical parameter of a food industrial product which is characteristic for an in-process production phase.

In the course of the complex failure analysis the common variations should be separated from the sporadic and the dangerous ones. If the common causes are known the process capability can be determined (assuming appropriate 'target value'). If the sporadic causes are known the critical (ABC-Pareto), the typical (TIPHIB) or the risky (FMEA) common causes might be chosen as well as the Ishikawa analysis can be done. Without knowing them the practical controls and actions could not be realized.

The experiences show that this phase requires the most work and time during the entire improvement project and the most teams are here necessary. Only a longlasting systematic (e.g. continuous improvement in line with PDCA-cycle at every area and level of the system) failure analysis and the corrective/preventive actions based on it can lead to such a rather low and more or less stable level of failures, causes and non-conformities where the next 'floor' (striving for controlled process) becomes a real objective.

It should be mentioned that in the course of this complex failure analysis process not only the level of the failures, non-conformities, scrap, causes have to be reduced but also the run of the failures has to be changed. When getting to the final phase of the improvement phase the most of the processes, produced items, products should follow an exponential-characteristic run instead of the mixed distribution of the starting phase.

The following figures show the starting, medium and final failure run characteristics of a one and a half-year quality improvement project. (The arrows mark the direction of the step to be followed.)

Here we got to the final tactical aim: the state of the controlled and/or capable process.

During the previous hundred years three generations of quality control have grown up.

The first generation can be linked to the name of Shewart who worked out the control chart systems for subsequent measuring of certain quality parameters of the end-products or partly finished products. The control chart was proper for the comparison of the sample statistics with the limits which were defined for the possible common cause control zone of the process. Based on this comparison taking into account the significancy analysis of the statistical tests the controlled state and the sporadic variations of the process could be evaluated. In case of



Fig. 2. Separation of common, sporadic and dangerous variations in the practice

sporadic causes (points outside the control limits) actions had to be done in order to correct the effect of the sporadic causes. Basically this is subsequent control of the measured quality parameter through negative feedback at a certain quality inspection point.

The process-oriented systems of the high-volume productions developed the individual control charts toward the so-called second-generation control method.

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Fig. 3. Trend of the failures (scrap, ppm, non-conformity) in the course of the quality improvement project

This was the SQC (Statistical Quality Control) where the individual control charts were harmonized at each point of the total manufacturing process and were fit to the controlled state of the end-product parameters. There was an effort to ensure the control in the process as early as possible to achieve that the following process step gets a part, product or unit with more stable and controlled quality parameters.

In the 70's appeared the 'third generation'. The reason is that not just the quality parameters have to be controlled on a process-oriented way but a higher level of the control should be realized. It means that if the process parameters (P) are under control we got a stable quality state (Q) and this is called SPC (Statistical Process Control). This approach strives for controlling the process or system parameters which determine the quality parameters. For instance the stability of suppliers, human resources, technical background are to be ensured. (Many experts refer to the need to ensure the control of 7M or 9M.)

It can be seen that a higher level generation involves the previous one and that a system which has controlled processes is the key factor of the stable and controlled quality.

It has to be noted that today the expression of SPC (e.g. SPC-sheets, SPCsystems, SPC-methods) is usually used in case of control chart-based or maximum SQC-type systems and methods in Hungary!!

Before the coming case examples the notice should be taken to consider the above explained theoretical principles when choosing from the three generations.

(Of course, implementation and operation of an SPC-system is a harder and more time demanding quality project than using of individual control charts for certain critical quality parameters. Only the SPC-system results in a stable and controlled system on long term while the SQC can achieve the harmonized control of the quality parameters within the frame of the given process parameters. It is also probable that the SPC-level might be reached only through covering the previous two generations.)

The following control assessment and analysis give answer whether the system is controlled or not while the capability analysis and evaluation show quality capability of the given system in the controlled state.

The aim of the first steps of the analysis is to discover, assess and rate the 'quality capacity' and reserves based on a static, passive information and database. According to that it is possible to determine the reserves and the quality improvement strategy which is necessary to apply [9].

In the second step of the analysis it is advisable to determine the absolute values of the (process and machine) capability and compare them with the customer requirements usually through the c_p (c_m) and c_{pk} (c_{mk}) indicators.

$$c_p = \frac{\mathrm{TM}}{6\sigma},$$

 c_p = process capability indicator

 $\dot{T}M$ = tolerance of the quality parameter

 σ = standard (theoretical?) deviation of the qual. parameter

Then it is possible to decide whether the system may be taken from an uncontrolled and uncapable state to a controlled and capable one or the system is under control and capable at the moment. The result of this assessment can be that it is worth to start the implementation of a control chart-based or SQC or SPC system.

The control is a characteristic feature of the system while the capability is the best state of the system which can be achieved in the given circumstances (perhaps only after great improvements). The relative features of the capability can be analyzed through the comparison with the customer requirements because it had to be deployed from the customer needs.

There were significant changes respect to the capability in the outstanding sectors (like electronics, domestic appliances, automobile industry, computer technics and parts) as it is represented by the following table:

time	c_p value	$\pm \sigma$	within (min.) %	without (max.) %	ppm
1970	1	3	99.73	0.27	2700
1980	1.33	4	99.999936	0.000064	
64					64
1990	1.64	5	99.999994	0.000006	
6					6
2000	2	6	99.9999995	0.0000005	0.5

The last row means the it is allowed to produce 1 non-conform product/service from a 2 million lot.

The next approach groups the types of the controlled/capable states of the systems:

	capable	not capable
	(C)	(NC)
controlled	CO-C	NC-CO
(CO)		
uncontrolled	UCO-C	NC-UCO
(UCO)		

We summarized the objectives, tasks and methods of the three-phase process which are suggested to the capability analysis in the following figure:

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Capability analysis of production systems/1:

Purpose of the Phase Static, passive data assessment Dynamizing, grouping into part-lots Assessments without limited, controlled actions *Methods* Statistical description Experimental distributions

Statistical indicators

Correlation analysis

Quality capability analysis and assessment

Decision 1

Capability analysis of production systems/2:

Purpose of the Phase Stability and set analysis

Get dynamic part-lots

Control and capability assessment, strategy choosing Oriented control exper. *Methods* Cause and effect analysis Statistical-based analysis of mixed distributions Hypothesis analysis Statistical tests Control Charts

Decision 2

Capability analysis of production systems/3:

Purpose of the Phase Absolute quality, machine and process capability analysis and assessment $c_p \ c_{pk}$; $c_m \ c_{mk}$ Active, dynamic exper. plans

Oriented control exper.

Methods

Design of experiments

Taguchi methods

SQC, SPC systems SQC, SPC methods, strategy change

Decision 3

Fig. 4. Phases of the capability analysis of production and service systems

The steps should come after each other. If the results of a phase do not make possible to go to the next step the quality strategy should be reconsidered and

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redesigned (because the quality keeping strategy is not realizable).

In this case usually it is necessary to plan and realize a new quality improvement-development project. In the Hungarian practice it is apparent that fortunately there are (interim) improvement opportunities within the system. Therefore the quality improvement strategy requires long time and external (financial, human and information) resources, too [5] [6].

There are coming some case examples for the control and capability analysis.

Fig. 5 and 6 show the dynamic diagrams of an uncontrolled and not capable powder-filling process. These are median-range control chart but are not SPC-sheets! *Fig.* 5 represents the median which refers to the actual state of the process and the *Fig.* 6 shows the concerning range. *Fig.* 5 proves the uncontrolled state while *Fig.* 6 makes visible the lack of capability (the ranges increase as a trend).

Fig. 7 is the opposite of these: it represents the scrap values of a product from the building industry. As it can be seen the process is capable and controlled. However, it is a next question whether the value of this capability fulfils the customer requirements!



Fig. 5. Median values of a not capable and uncontrolled process

Fig. 8 shows the state-distributions through the critical parameter of a controlled but not capable (the required minimal c_p value = 1) automobile-production process via another type of chart. It is not a dynamic run-chart and is not a control chart but it contains the distribution-curves of a longer period. There is a supposition by the teams after a long-term quality improvement project that the process is stable and homogeneous (as in the case of example of *Fig.* 9, too).

Fig. 9 represents the model of an uncontrolled but capable process through the critical quality parameter of a paper-industrial product.

Finally, *Fig. 10* shows a process improvement project started from an uncontrolled and not capable state which seemed to be unhopeful respect to the automobile-supplying plans of the manufacturer company. The process was 'attacked' by an improvement project two times and the result is: first a control chart-based then an SQC-oriented system. This is the evidence of the hidden qual-

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Fig. 6. Range values of a not capable and uncontrolled process



Fig. 7. Capable and controlled process via attribute (scrap) control chart

ity improvement potentials which may be discovered by a systematic quality improvement/development project in a Hungarian quality management system. (The mentioned four-phase project lasted for four years at the company that was as ISO 9001 certified. The company is still an 'A' category supplier of a leading European automobile manufacturer company.)

The first state of the figure shows the starting state supposing a simulated conformity based on the comparison of former manufacturing results with the customer requirements. Taking it as a basis the first quality improvement project was started which aimed the discovering of the factors that cause the extremely high deviation. The second state of the figure shows the results of the actions after the analysis. In the following step the team stated the setting and the factors which influence the mean into the center of the quality improvement project based on the preliminary results. The actions coming after this analysis refer to the good work of the team. Even more, it seems that the factors influencing the mean have an impact on the deviation because it was also reduced. After that the team decided about

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Fig. 8. Distributions of a not capable but uncontrolled process and its c_p values



Fig. 9. Distributions of a capable but uncontrolled process and its c_p values

the implementation of the control chart-based system (median-range chart). Then based on its experiences and taking into account the methods which are required by QS-9000 and VDA 6.1 an SQC system was worked out for the given critical parameter.

So, which one should be the Hungarian model?

What should be the Hungarian Model/1?

- a Striving for TQM;
- from Europe: the 'core level' is the middle-management;
- from Japan: PDCA teams applying the '7 best problem solving tools';
- from America: building up the necessary 'management climate'.





Fig. 10. From a not capable and uncontrolled process to a capable and controlled process via quality improvement project

What should be the Hungarian Model/2?

- weight on the conditions of the quality management and control
- practical realization of the 40-30-20-10 ratios of the systempyramids
- spending 10–25% with the establishment of the quality culture through using of the necessary special methods invoving continuous participation (CQI-CIP)
- key-process teams, top management team, quality system and methods team.

What should be the Hungarian Model/3? Continuous Internal Quality Development:

Continuous reduction of the non-conformity level through the identification of the dangerous variations via complex failure analysis based on a reliable data and information basis as well as hereby to establish the way to the 'zero-defect' controlled and capable processes.

This study does not deal with several methodological and model-related approaches of the above explained issues (e.g. system pyramids and their rates, the three quality direction, special models of the quality improvement (CWQI-CIP, principles of TQM). These topics are worked out by the referenced papers which are also contained by the list of Literature [4] [7]–[10].

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