Complex methodology of "cycled-through" quality management in the framework of 9000 iso standards

Pavel S. Serenkov,

Doctor of Philosophy in Technical Science Pavel Serenkov@mail.ru, tel/fax: +375 172 32 22 01

Adresse professionnelle

Belarusian National Technical University ★ 65-17 Fr. Skaryna Ave. ★ Minsk 220013, the Republic of Belarus

<u>Résumé</u> : Dans cet article, il est proposé une présentation des étapes qui composent et articulent le cycle de la direction de la qualité. Une attention particulière est accordée à la dernière étape à savoir, l'élaboration du mécanisme d'acceptation effective des décisions prises par rapport à la qualité. On propose la conception d'un modèle de l'acceptation des décisions sur la base des prétendants dans des conditions d'incertitudes.

<u>Резюме</u>: В статье сформулированы (определены) 4 этапа «сквозного» цикла менеджмента качества. Особое внимание уделено последнему этапу – разработке эффективного механизма принятия управленческих решений в отношении качества. Предлагается концепция модели принятия решений на основе «прецедентов в условиях неопределенности».

<u>Mots-clé/key-words</u> : qualité, conception, l'incertitude, modèle décision ; quality, conception, uncertainty, decision making model.

Complex Methodology of "Cycled-Through" Quality Management in the Framework of 9000 ISO Standards

An increased interest to new information technologies of quality management (QM) has been observed recently. This has been determined by at least two factors: on the one hand. ever-growing competition and corresponding market pretensions to a manufacturer; and on the other hand, expansion of the ISO 9000 standards, which have demanded new forms and methods of resource mobilization, control mechanism reorganization, business structure rebuilding etc.

A lot of really impressive examples of economic efficiency resulted from implementation of quality management systems appeared in Belarus. The system developed and deployed in accordance with the requirements of the 9000 ISO standards is the effective increasing tool for of competitiveness.

Unfortunately, nowadays there is a rather hard skew in this direction of activity in our country. The top management of many enterprises hastens to apply in industry the quality management systems with the purpose just of obtaining the certificate of quality conformance.

One of the main reasons of this is the absence of complex methodology of QM, which would be based on classical principles of management. In our opinion such kind of a scientifically founded methodology is the methodology of a "cycled-through" QM. This methodology must be presented as a typical program in quality activity domain. Conceptually the methodology includes a complex of sub activities, technical methods and informational technologies, integrated into Deming's management cycle "P-D-C-A".

In our point of view there must be 4 stages of this cycle.

1.- business-processes identification and description (i.e. building of a "network of processes" functional model, which defines processes, resources, owners, relations)

This stage has been well worked out by us. For process network description we recommend a methodology of function modeling basing on the IDEF0 standard. In the framework of National Standard Committee "Quality Management" we have developed a corresponding methodic manual.

2. - deployment of QM System as a totality of structure, methodologies, processes and resources.

3. - measurement, inspection, evaluation with the help of acquisition and registration data subsystem.

The second and the third stages have been well methodically worked out in the practice of organizations of Belarus and noted at the correspondent methodic manuals of National Standard Committee "Quality Management".

4. - Effective decision making (including corrective and preventive actions) on the basis of factual data.

Unlike the others it hasn't had essential scientific and methodological work out. Most often this process isn't formalized. That's why management today is more an art than a formalized and well-grounded process.

Stated peculiarities determine appropriateness of usage of fuzzy formalization methods, based on practical experience. We recommend modeling by precedence under uncertainty: comparison of the current situation with the known examples and decision making, corresponding to a similar example. Modeling by precedence is realized in the framework of the mathematical theory of pattern recognition on the basis of functional model (the first stage).

Development of this mechanism's successful model is the missing link in the "cycledthrough" QM methodology.

1 – INTRODUCTION

The quality management as "action" assumes first of all complex solving of the tasks of

planning, support, manual and improvement of quality of each process and network of processes as a whole, forming so-called cycle, "P-D-C-A". Integrated approach is the main principle of construction of quality systems. In turn each stage of cycle "P-D-C-A" is based on expansion of a subsystem of collection, analysis and generalization of the data about quality, framing and making decisions, organization of correcting and warning effects and control of their efficiency. As a result the manual of quality in the company represents a rather complex system of the interconnected procedures "serving" the network of processes, defining quality of finite products. This aspect is especially underlined and makes the basis of the projects of 9000 ISO standards of the version 2000

Effective solution of such problems is possible in modern conditions only with usage of socalled information technologies. Now special attention in the world is given to theoretical and practical operating time in the field of quality management. Today it, perhaps, is a unique real source of the unused internal spares deciding questions of an effective manual by the company. The analysis of the market of information technologies of management has shown, that, as a rule, they are " know - how ". In order to work successfully market in the modern organizations are forced to buy and to use existing theoretical and practical operating time of the leading companies, and also to initiate creation of new technologies, which costs not cheap for them.

An increased interest to new information technologies of quality management (QM) has been observed recently. This has been determined by at least two factors: on the one ever-growing hand. competition and corresponding market pretensions to а manufacturer; and on the other hand, expansion of the 9000 ISO standards, which have demanded new forms and methods of resource mobilization, control mechanism reorganization, business structure rebuilding etc

Basic management methods, formed in the 60s – 70-s of the past century, can't by themselves provide an effective control of organizations nowadays. This is caused by the fact that most organizations represent complex man-machine systems. Their functioning depends on a great number of weakly formalizable dynamic factors. As a rule, there's no possibility to reveal and promptly characterize all these factors a priori. As a result, OM has to be implemented under uncertainty. In this case OM is realized on the base of current observations and turns into online correction of controlling in response to functioning quality discord. The need to formalize this process dictates the necessity of advancement of the existing models and methods and the development of new ones. To solve these problems we need to use presentday mathematical theories including the theory of artificial intelligence.

One of the approaches to problem solving is proposed in the paper.

2 – QUALITY MANAGEMENT IN THE ISO 9000 STANDARDS

According to the ISO standard (ISO 9000 family standard, 2000 edition) OM represents an interrelated procedures system, "serving" a network of processes which define final product quality. QM implies complex solution of such problems as: planning, assurance, control and improvement of quality of processes, which form the so-called E. Deming's control cycle (or "P-D-C-A") (fig. 1). Each stage of the "P-D-C-A" cycle is based the following subsystems on deployment: acquisition, registration, analysis and generalization of appropriate data [1-3].

The first stage aims at creation of a functional model of organization business-processes. The model is intended for the formal description of business-process structure (of constituting subprocesses and their relations), and also of all information flows and material flows circulating in it. This stage has been well worked out. In particular for the modelbuilding, a methodology for process network description basing on the IDEF0 standard has been developed [5].

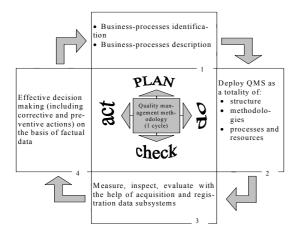


Fig. 1 Concept of quality management methodology as a control loop in the view of supplier organization

What does it mean to define and control the network of processes of organization? The 9000 ISO standards answer this question so:

• To install and hierarchically to draw up processes, which directly define quality of finite production;

• To define"inputs" and "outputs" of these processes, their interrelation;

• To identify each process on such aspects, as:

- 1. Responsibility;
- 2. Resources;

3. Documentation (organizationcircumspect documents, rules, specifications, technique, etc.);

4. The complex of quality metrics of the process (that is inspected, how, how often and where registers);

5. The place of the given process in the network of processes (what moves on an input, whence, what is on an output, where goes etc.).

The methodology of the functional processes modeling - IDEF0 (Integrated Definition for Function Modeling), on our sight, mostly approaches for solution of problems of maintenance in working order and certification of quality systems corresponding 9000 ISO standards and considered as systems of network of processes manual. The methodology IDEF0 favorably differs from others is accepted as the federal standard of USA and is considered in ISO as the international standard. In a basis of the

IDEF0-methodology lays the concept of the block. modeling defined "business function", which transforms "input" to "output", being guided "control" (documents), using "mechanism" (financially - technical, human etc. resources) (fig. 2). It is obvious, that the methodological approaches IDEF0 and quality management, as the manuals of the network of processes in organization, are identical, what is very important and attractive, for example, for the purposes of certification.

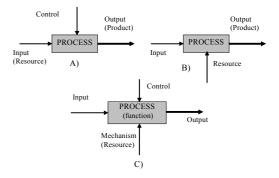


Fig. 2 Concepts of processes manual according to:

- A) ISO 9000 Introduction and Support Package: Guidelines on the Process Approach to quality management systems. ISO/TC 176/SC 2/N 544R.
- B) ISO 9000 Program for developing countries. Proceedings of International Conference, Gosstandard of Republic of Belarus, Minsk, 2001.
- C) The conception of modelling the processes (INTEGRATION DEFINITION FOR FUNCTION MODELING (IDEF0). Federal Information Processing Standards Publication 183, 1993.

A CASE-resource IDEF0/EMTool (graphics DBMS) powerful by possibilities and simple in usage is developed on the base of IDEF0. Attractiveness of this tool for the quality service, as however of any other structure of organization irrespective of the profile of activity, consists in that it is reckoned on the user knowing how to work in the environment Windows, but not having skills in programming. IDEF0/EMTool is powerful by possibilities information system for the quality service of organization permitting to make the project of the quality system as networks of processes visual (transparent), coordinated,

"ready" to the regular analysis, further improvement.

The experts of the Byelorussian National Technical University together with the developers of IDEF0/EMTool developed the methodology of modeling, description, analysis and perfecting of processes within the framework of the quality system corresponded to 9000 ISO standards.

The second and the third stages have been also well worked out in the practice of organizations of Belarus, Russia and other countries [4].

The fourth stage is connected with efficient managing decision-making (corrective and preventive actions) on the base of feedback. Unlike the others it hasn't had essential scientific and methodological work out. Most often this process isn't automatized and entirely realized by manual labor. That's why management today is more an art than a and well-grounded formalized process. According to the seventh of the QM principles corrective and preventive actions should be based on "factual data". Development of this mechanism's successful model is the missing link in the "through" QM methodology.

Conceptually managing decision making mechanism lies in the following: management efficiency used depends on the process state. The process is implemented as a transition into one or another process state. In general change of process state demands new managements. Decision making is realized on the base of a current process state assessment. The process state is defined by set of internal conditions (those connected with the manufacturing system directly) and external conditions (connected with system functioning environment). Let's call a set of these conditions a situation. It is characterized by the set of measurable parameters (situation description) being informational state vector. Under the unpredictable process change condition situational management can be used for decision making:

- current state monitoring and identification of the moment of transition to a new state;
- making new decisions which are adequate to the current situation.

QM has at least two interconnected and subordinate contours of management:

- "general quality management" first level loop, expressed as QMS requirements (ISO 9001:2000);
- "local quality control" second level loop, is specific in the methods, approaches, tools.

"General quality management" loop purpose is effectiveness assurance in general. It realizes integrated approach to quality management irrespective of the type of output product, life cycle peculiarities, organization structure, property type etc. The sphere of the loop application is network of processes constituting organization business process. general According to ISO 9001:2000 management is realized on the following levels:

- strategical management (which is realized as requirements of the clause 5 "Management responsibility");
- resource management (realized as requirements of the clause 6 "Resource management");
- operative management or controllable conditions assurance (realized as requirements of the clause 7 "Product realization");
- measurement, analysis and improvement (realized as requirements of the clause 8 "Measurement, analysis and improvement").

"Local quality control" loop is not specified in ISO 9001:2000 and that's why it is not restricted in methods, approaches, tools. The loop's purpose is assurance of the whole business-process quality and its particular subprocesses. It is aimed at the organization competitiveness enhancement and implements an integrated approach to the quality management under particular conditions, determined by internal factors as well as external ones.

"General quality management" loop is more formalized. It is more capable of automatization and can be first of all considered as research object.

3 – QUALITY MANAGEMENT MODEL BY PRECEDENCE

The role of the general quality management is to assure (in terms of given criteria) the conformance to ISO 9001:2000 requirements of clauses 5-8 through the whole businessprocess.

It is assumed that for each particular requirement expert scores are given, which characterize its quality of conformance. Scores are measured in some scale and can be defined (e.g. on the ground of audit findings) in any current moment of manufacturing process. There is a limit defined for each requirement, which indicates acceptable deviation from the maximal score.

According to the typical situation we assume that process transition into a new state can occur in any random point of time and is determined by a set of unknown uncontrollable factors. As a consequence there's no possibility to identify the reasons.

Process state change as a rule violates a degree of conformity to some requirements. That's why appropriate managing actions should be taken during system functioning. They are determined by either observed process dynamics or are based on forecasting or can be of the following character:

- preventive (preventive actions),
- corrective, i.e. be as an answer to occurred changes (corrective actions or corrections),
- character of planned process and/or product improvement (improving actions).

As a result the task of management (on a general quality management level) can be reduced to the tracking task. The essence of this task is real-time change of process state in response to nonconformity to ISO 9001:2000 requirements.

This task can be formulated in the following way.

Let P is a complex process of general quality management; X – a set of its acceptable states; $C(X) = \{c:X \rightarrow X\} - a \text{ set of acceptable control}$ actions (corrections); R – a set of ISO 9001:2000 requirements, corresponding to "general quality management" loop (fig. 3); Q:R×X \rightarrow [0,N], N<+ ∞ – quality assessment of compliance of requirements r from R in different states x from X.

It is required to realize the following equation $c^*:X \rightarrow X, c^*(x) \in \{x\} \cup \{c(x), c \in C\}$, which for every x from X assures the following terms

$$Q(r,c^{*}(x)) \ge a_{r}, \forall r \in R$$
(1)

where $\{a_r\}_{r\in \mathbb{R}}$ is a set of given parameters.

The task solution is in creation of local efficient complex control action (control) in the form of sequence of corrections, adequate to the manufacturing process dynamics. Under unpredictable dynamics condition it is reasonable to use control based on a current state observation and analysis.

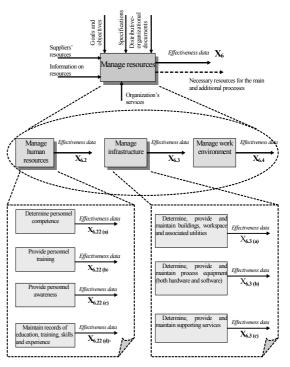


Fig. 3 Segment of "general quality management" model – decomposition of one of the four "resource management" control processes (clause 6 ISO 9001:2000 "Resource management"; indexes correspond to numbers of requirements' points)

Thereby two main subtasks arise:

- detection of system functional "discord", i.e. violation of term (1) (discord problem),
- automatic choice of locally efficient correction, restoring term (1) (problem of choice).

While developing approaches to these tasks solution we can proceed from the following "general quality management" loop peculiarities:

- effectiveness of the control loop (of management system operation in the whole) is conditioned by a great variety of weakly formalizable factors (fig. 3);
- relation between effectiveness and these factors is weakly formalizable, what along with the previous peculiarity makes the effectiveness estimation "poor", i.e. lowinformative;
- loop is specified in ISO 9001:2000 [2], what determines general management mechanism stability and allows to use the accumulated experience.

Stated peculiarities determine appropriateness of usage of fuzzy formalization methods, based on practical experience [3].

Most often experience is represented by examples of successful manufacturing situations with corresponding corrections indication. If that's the case, discord situation identification and adequate correction selection are based on modeling by precedence: comparison of the current situation with the known examples and decision making, corresponding to a similar example.

Modeling by precedence is realized in the framework of the mathematical theory of pattern recognition. Primary task is to build informative space of attributes to describe set X of acceptable process states.

Here the task of detection of observed informative parameters, which reflect general management quality, arises. The problem lies in the usually unknown relating mechanism between observed process parameters and type of adequate correction. This does not allow to identify acceptable subset of indirect attributes. That's why it is suggested to use general management efficiency-performance factors described as ISO 9001:2000 requirements (clauses 5 to 8) as attributes for situation description.

Then state $x \in X$ is described by vector of the following type $(x_1, ..., x_N)$, including the four attribute groups:

1. $x_1, ..., X_{N_1}$ - attributes, corresponding to the clause "Management responsibility";

2. $X_{N_1+1}, ..., X_{N_2}$ – attributes, corresponding to the clause "Resource management";

3. $X_{N_2+1}, ..., X_{N_3}$ – attributes, corresponding to the clause "Product realization";

4. $X_{N_3+1}, ..., X_N$ - attributes, corresponding to the clause "Measurement, analysis and improvement".

Tolerance region of attribute x_i , $1 \le i \le N$ is defined by set of acceptable numerical scores of i-attribute. Scores characterize quality of requirement compliance and are usually defined by finite number of integral values.

Let $X_0 = \{X_i^0\}_{i=1,..,K}$ is a set of known states, used as an examples.

Initial information is $T=\{\langle m_{i1}^{o},...,m_{iN}^{o}\}$

), $a_i > \}_{i=1,2,...,K}$. Here m_{ij}^{o} , $1 \le i \le K$, $1 \le j \le N$ is a numerical score, characterizing degree of conformity to j-requirement in state x_i^{o} , and a_i is a description of corresponding x_i^{o} corrections. As each clause of "general management" requirements has its own corresponding control, a_i is like $(a_{i1}, a_{i2}, a_{i3}, a_{i4})$, where $a_{i1}, a_{i2}, a_{i3}, a_{i4}$ is control according to each of four clauses. Set $A_j = \{a_{1j}, \ldots, a_{T_jj}\}$, $1 \le j \le 4$ of acceptable corrections is formed by experts. For states x_i^{o} , which don't demand corrections, it is assumed that $a_i = (0, 0, 0, 0)$.

In the context of disorder problem set X of acceptable states allows splitting into 2 classes

$$X = X^+ \cup X^-.$$
 (2)

Here X^+ is subset of normal states, and X^- subset of discord states. The first one corresponds to a set of desirable process states when no corrections are needed. The second corresponds to set of states which do not conform to the required quality and demand appropriate corrections. Disorder problem is solved by constant manufacturing process monitoring. Direct testing of term (1) for the current state $x \in X$ is rather time-consuming task. Two-level solution of disorder problem is proposed:

- manufacturing process current estimation on the basis of rather simple heuristic algorithms (current monitoring) and
- direct testing of term (1) (total audit).

One of possible approaches to monitoring consists in classification of the current state with respect to splitting (2). Thereto we can use recognition with training. On stage of training to class X^+ refer $x_i^o \in X_o$, for which $a_i=(0,0,0,0)$, and to class X^- - all other states.

The decision rule is formed in the following way. On the base of expert analysis each attribute group $\{x_1,...,x_{N1}\}$, $\{x_{N1+1},...,x_{N2}\}$, $\{x_{N2+1},...,x_{N3}\}$, $\{x_{N3+1},...,x_N\}$ is associated with one or more integral attributes. They provide rough (but easily calculated) estimate of requirements' feasibility of appropriate ISO clause in the whole.

Hence, at any current point of manufacturing process all the "general management" loop requirements should be fulfilled, X⁺ consists of which attribute values elements, are sufficiently close to the maximum. For X⁻ elements this condition is untrue at least for one of the attributes. Thus, for the classification of the current state $x \in X$ with respect to splitting (2), acquired at the training stage, we can use e.g. "nearest neighbor" method scheme with proximity function μ : \mathbf{v} 17 \mathbf{D} μ(6

$$((\mathbf{x}_1,...,\mathbf{x}_n),(\mathbf{y}_1,...,\mathbf{y}_n)) = \max_{i=1,..n} (\mathbf{x}_i - \mathbf{y}_i),$$

Precise diagnostics of discord situation (total audit) is held in certain specified time periods or in emergency cases, indicating flat violation of general management maintenance.

In order to solve the problem of choice, recognition with training can be used.

As "general management" loop is split into 4 independent clauses, and realization of each demands its own corrections, it is proposed to consider individual problem of choice for each of the clauses. Totality of corrections obtained makes up an integrated managing decision on "general management" provision. At training stage 4 splittings of a set X⁻ into clusters of similar situations are formed: according to attribute groups $\{x_1, \dots, x_{N_1}\},\$ $\{x_{N1+1},\ldots,x_{N2}\}, \{x_{N2+1},\ldots,x_{N3}\}, \{x_{N3+1},\ldots,x_{N}\}.$ Each of them is conditioned that situations in one cluster are to have corresponding equal control. Possibility of such splitting construction is conditioned by the following factors. Effectiveness of the control action depends on system state. Manifestations of different system states in their diversity exceed greatly the number of acceptable controlling decisions. While the latter have a certain stability, and as a result one and the same control is effective in rather close situations. Splitting reduces to clusterization with the outer aim without a tutor. In order to solve it we can use the "dynamic nuclei" method scheme.

The choice of correction in current state $x \in X^$ is reduced to its subsequent classification with respect to each of the four obtained splittings of X^- . According to the results of the classification with respect to one or another splitting control action, which assures conformance to corresponding group of requirements is chosen. Totality of solutions, obtained after these classifications, makes up the solution of the problem of choice.

4 – CONCLUSION

The two control loops in a quality system condition existence of the two types of manufacturing process control problems: control tasks on the general management level and control tasks on the engineering-technical personnel level. Each of them can be formulated as a tracking task, which aims at usage of optimal/suboptimal (with respect to given efficiency criteria and on given set of allowable alternatives) control action at any current stage of manufacturing process. As each loop has its own "bottlenecks", efficiency criteria and initial data, the tasks require solution techniques. However. different decision-making scheme general by precedence is applicable in both cases. At the engineering-technical control level it can be used under conditions, when reason for discord from the objective can't be identified and choice of control action is realized in dialog mode on the basis of special analysis of the current state. Observed product quality figures

in this case can be used to describe current manufacturing state.

REFERENCES

- [1] ISO 9000 Introduction and Support Package: *Guidelines on the Process Approach to quality management systems*. ISO/TC 176/SC 2/N 544R. 17 May, 2001.
- [2] ISO 9001:2000(E) Quality management systems - Requirements.
- [3] Krasnoproshin V.V., Maksimovich E.P. Decision Making by Precedence in Problems of Control of Discrete-Event Systems. – Preprint/ Institute of Cybernetics of NAS, №7 – Minsk, 2000. – 42 p.
- [4] Serenkov P.S., Solomaho V.L., Krasnoproshin V.V. "Cycled-Through" Quality Management Model magazine "News. Standardization and Certification", №5, October 2003 Minsk, Belorussian State Institution for Standardization and Certification, 65-69 p.
- [5] TC RB 4.2-R-05-2002. *Methodology* and of Operations Sequence on Determination, Classification and Identification of Processes. Processes' Description on the Basis of IDEF0 Methodology. - Methodical Recommendations. STC of Standardization "Quality Management" of Committee for Standardization, Metrology and Certification of Republic of Belarus. 2001.