Development of Management Methodology for Engineering Production Quality

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Abstract. The authors of the paper propose four directions of the methodology developing the quality management of engineering products that implement the requirements of new international standard ISO 9001:2015: the analysis of arrangement context taking into account stakeholders, the use of risk management, management of in-house knowledge, assessment of the enterprise activity according to the criteria of effectiveness.

1. Introduction
The quality of engineering products largely determines the effectiveness of a country industry because engineering creates a technological basis of all industries [1]. A successful management of a machine-building enterprise requires that it is carried out systematically and in an apparent way. The best world experience shows that success in business can be achieved only through implementation and maintenance of the quality management system (QMS) that confirms the requirements of international standard ISO 9001. Up to date, there have been published four versions of this standard: in 1987, 1994, 2000 and in 2008.

In September, 2015, a new version of standard ISO 9001: 2015 was enforced, which includes new conceptual requirements, compared with the previous version: the analysis of the organization context, understanding the needs and expectations of stakeholders, risk management, knowledge management, performance assessment, etc. The implementation of these requirements at a machine-building enterprise faces methodological difficulties [2]. Therefore, the authors of this article offer the directions for methodology development that provide implementation of the requirements of quality management standard ISO 9001: 2015.

2. Analysis of the Organization Context Taking into Account Stakeholders
ISO 9001: 2015 includes a section ‘Organisation Context’ which requires from the Organisation to understand the needs and expectations of stakeholders in its functioning. For this purpose the Organisation should identify the stakeholders relevant to the QMS, define their requirements, monitor and analyse the information to meet their requirements.

The quotient of satisfaction of all stakeholders is becoming a global criterion of perfect (optimal) activities of any organisation in economically developed countries. This quotient should be measured (assessed) quantitatively. Measurement techniques of this indicator are currently still underdeveloped. In order to solve this problem, it is proposed to use a technique [3], in which the assessment of the satisfaction degree of all stakeholders in an organisation is done using a complex criterion, representing a weighted average amount of local criteria of the satisfaction degree of stakeholders:
consumers, employees, owners, partners, suppliers, society. There are constructed hierarchy schemes of local criteria interconnection with weights of importance. The assessment of local criteria at a lower level in the hierarchy is made by experts using fuzzy sets.

After the initial assessment of stakeholder satisfaction it is necessary to solve the following task of QMS optimization [4]: ‘QMS will be optimal if there is a set of regulatory requirements to key processes of the QMS (management responsibility (leadership), resource management, product life-cycle processes, measurements, analyses, improvements), which gives harmonic integrity of degrees (indexes) of stakeholder satisfaction, that presents the balance of values of local stakeholder satisfaction criteria among themselves, taking into account their subordination and respective proportions, when none of the requirements for the processes cannot be changed (increased or decreased) without violating the integrity of an optimal composition”. A minimax algorithm is used as a search method for effective solutions (the compromise).

3. Application of Risk Management
A new requirement, which is found in many sections of ISO 9001:2015 is the need for application of risk management in QMS (the concept of risk-oriented thinking), which replaces the warning action. To meet the requirements of this international standard, the Organisation should plan and implement actions in response to risks and opportunities. Responding to risks and opportunities, creates the basis for increasing QMS effectiveness, achieving better results and preventing negative effects.

The risk management process consists of the following steps (ISO 31000:2009): 1. Information exchange and consulting with internal and external stakeholders. 2. Definition of the situation. 3. Risk identification. 4. Risk analysis. 5. Risk evaluation. 6. Impact on risk. 7. Monitoring. ISO/IEC 31010:2009 describes more than 30 methods for risk assessment. According to the authors of this article a well-known FMEA-Potential Failure Mode and Effects Analysis is the most suitable for risk analysis of quality management processes in engineering, because it allows identifying and evaluating QMS processes that may not perform the intended functions and do not meet the established requirements. However, FMEA has a substantial drawback. The matter is that this risk analysis is to be carried out by a group of experts (FMEA team) that identify risks, assess relevance score S, mark emergence O and discovery point (D) of each risk. Then they calculate the priority number of risks (PNR) by multiplying the points. However, as we know in Metrology, points are only fixed points on the rank scale, so they should not be used for any mathematical operations. As a consequence, the definition of PNR by multiplying the points is incorrect. To solve this problem the authors offer to apply the theory of fuzzy sets [5] to conduct FMEA and subsequent interpretation of the analysis results for quality management. Despite the apparent complexity of calculations, the proposed approach to defining FMEA is easily implemented in practice by using the simplest software.

4. Managing Company Knowledge
A new conceptual requirement of ISO 9001:2015 is introduction of knowledge management in QMS. The Organisation should identify the knowledge necessary for the operation of its processes and how it will acquire or receive access to additional knowledge and necessary updating of its knowledge. The development of the knowledge management system (KMS) is one of the priorities in the field of quality management. The establishment of KMS is a new and weakly developed problem [6]. To solve this problem, the authors suggest using a KMS structural model, which defines the following principles for its creation.

The core of KMS at an engineering enterprise is a multivariate corporate storage of knowledge in quality. The storage should provide a quick and easy search and also allows the storage of diverse information resources.

In its functioning KMS should form two flows of knowledge. Firstly, it enriches the storage, extracting knowledge from different sources. Secondly, it gives knowledge to users at their request or ‘on its own initiative’, identifying the need for available knowledge by indirect signs.
One of the most difficult practical problems when building KMS in a company is forming the base of knowledge. In this paper, it is proposed to accumulate knowledge (experience) as a result of task solution by various professionals using funds provided by the subsystem of work with frames. Other means of KMS should provide access to existing knowledge. Besides it is preferable not to search knowledge at the user's request, but using the task automatic provision of knowledge found through ontologies.

Knowledge acquisition by the system is performed using the search engine, retrieving, structuring and sorting out knowledge. This subsystem modules are designed to analyse sources and identify various models for knowledge representation.

Information resources in the storage are classified into three types: data, information and knowledge. There is no universally accepted definition of these concepts, so in this work, they are treated as follows:

*Data* – fact (indicator) which value (usually digital) is uniquely identified by a fixed set of measurements. Information is a formalised text in a human language, which describes properties and characteristics of analyzed objects. Knowledge is the rules, procedures and methods for solving problems in the field of quality, the need for which occurs in a company.

The concept of a frame of knowledge is used as a basic structural part of knowledge in the storage, which in a generalized form can be represented by a tuple of elements: a hierarchy of objectives, sub-objectives (criteria) and alternatives; a formalised description of the relative importance of the hierarchy elements; mapping of the set of names of slots and factors in a variety of formal descriptions that make up the information in KMS.

A frame from the ‘framework’ is transformed into specific knowledge by symbols (names) and ‘attribution’ slots, i.e. by assigning their elements-factors to particular values, connecting them with varying information from the storage (which may be replenished).

When using the knowledge frame the hypercube of knowledge of multivariate KMS storage is defined by six basic axes of measurement (participants, organisations, products, processes, time and human resources), which have been determined earlier. Each cell of the hypercube, resulting from the intersection of the basic axes, presents a set of previously solved tasks in the form of the vector of frames. In other words, the cell of knowledge hypercube represents a ‘book’ of ‘pages’ strung ‘on the axle of a problem.

Within KMS there have been developed frame models to solve the tasks of strategic planning in the Organisation's QMS, as well as solution models for the challenges of QMS processes improvement using KMS.

5. Evaluation of Enterprise Performance Based on Criteria of Effectiveness

In accordance with the requirements of section ‘Performance Evaluation’ of ISO 9001:2015 the Organisation should evaluate indicators of functioning and effectiveness of QMS. However, the existing methods have the problem of quantifying the value of deviations (change) of QMS effectiveness, which is undeveloped. Thus, this article proposes to apply the methodology for assessing the impact of changes on the basis of cluster analysis [7].

Evaluation of QMS according to this method is carried out by analysing the performance of the basic processes of quality management based on actual and planned values of group performance indicators. QMS processes are determined depending on the specific character of the organisation activities, which will apply the proposed methodology. QMS which will be certified in compliance with ISO 9001: 2015, will include the following processes: management responsibility (leadership), resource management, product life cycle, QMS analysis, management of inconsistencies, QMS improvement.

To calculate the performance of processes included in QMS, we should determine the performance criteria and significance of these indicators. As a criterion we should understand an indication or a rule, on the basis of which evaluation, definition or classification are carried out. Single performance indicators serve as these criteria. Group indicators are calculated as a sum of single indicators.

Evaluation of QMS performance begins with the definition of single performance indicators of QMS processes. To determine single performance indicators of QMS processes the following procedure should be done:
Define the process customers.
Define requirements and expectations of the process customers.
Formulate single performance indicators and formulas for their quantification on the basis of this information.

After defining single performance indicators of QMS processes the information should be gathered and calculation of actual and planned values defined as indicators needed to evaluate the impact of each process included in QMS. Then, according to the formulas for calculation of group indicators there should be determined the actual and planned values of performance of each process in the system.

After determining the effectiveness of all processes the value of changing QMS performance over the planning period is calculated. To determine the changes of QMS performance we propose to use one of the two elements of the cluster analysis. The first element is related to the definition of an extent of objects similarity, the second – to an extent of objects proximity in Euclidean space.

On the basis of the calculated indicators the conclusion on the degree of QMS effectiveness is made. If the analysis proves that the system functions inefficiently, the measures to improve the system functioning are taken in order to increase its effectiveness. If the results of the analysis reveal that operating system is ineffective, it is necessary to identify inconsistencies and their causes, as well as to develop and implement a set of corrective measures.

Application of the technique described above and quantification of changes in the effectiveness of QMS processes creates the possibility of efficient (monthly, quarterly and annual) planning and recording QMS performance in the departments of an engineering enterprise.

6. Conclusion
In general, a new version of ISO 9001 : 2015 is certainly a significant step forward in the development of quality management. However, the implementation of its key provisions, such as the analysis of the company context, risk-oriented thinking, leadership, knowledge management and other new concepts at engineering enterprises will cause certain difficulties. The implementation of the proposed in this article directions of quality management methodology development in order to ensure a balance between the needs and expectations of all stakeholders of the organisation, risk management introduction, knowledge management, evaluation of effectiveness of quality management processes, will allow the company to restructure its QMS in time (three years), established by ISO 9001: 2015.

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